THE FUNDAMENTALS OF …

Intravenous Pumps

Robert Dondelinger

One of the very first pieces of equipment the new biomed is likely to encounter is an intravenous or "IV" pump. It is one of the most common pieces of medical equipment found in a hospital or large clinic, found in the hundreds in large facilities (or in the shop awaiting repair), so it is about time the fundamentals of this device are revealed.

The basic IV setup consists of a sterile liquid source, formerly a glass bottle but nowadays a plastic bag, a drip chamber with an attached spike, a length of plastic tubing approximately 48 inches long, a roller clamp, an auxiliary clamp, one or more injection ports, and a needle end. This setup depends on gravity to deliver a prescribed liquid directly into the patient's vein. The liquid source is generally a disposable container holding a liter of a prescribed fluid. This fluid can be normal saline (9 g of salt per 1000 mL sterile water added to provide a 0.9% saline solution, the same salt concentration as body fluid), to provide simple hydration. A solution of 5% dextrose in water (D5W) is used to provide both hydration and basic nutrition. Another common fluid is Ringer's lactate (also called lactated Ringer's or Hartmann's solution) which consists of sterile water with calcium chloride, potassium chloride, sodium chloride, and sodium lactate added— typically used for rapidly restoring lost blood volume and depleted electrolytes.

The drip chamber containing the bag spike performs two functions. One is to penetrate the seal of the sterile liquid source. This allows fluid to enter the drip chamber through an integral needle. When properly set up, the drip chamber is approximately half-full of fluid with air taking up the remaining space. When hanging, the drip chamber supplies the IV tubing with fluid.

The roller clamp totally surrounds a short section of the IV tubing and contains a slanted raceway holding a small knurled wheel. When the nurse rolls the wheel all the

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Intravenous or "IV" pumps are one of the most common pieces of medical equipment.

way down to the bottom of the clamp, it pinches the tubing totally closed. When the wheel is moved all the way to the top of the clamp, the tubing is totally open. Normally, the wheel is adjusted to a position between fully closed and fully open so that the number of drops falling from the drip chamber's needle to the pooled fluid below will deliver the prescribed volume.

The auxiliary clamp allows nursing staff to temporarily stop the IV without affecting the rate adjustment. The injection port provides a means for injecting medication from a needle and syringe or adding a burette piggyback IV, and a needle end, which connects to the needle or catheter placed in the patient's vein.

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If we assume that the physician ordered 1,500 mL of normal saline to be infused over 12 hours, which equates to the administration of 2.0833 mL per minute, the nurse would use a regular IV tubing set where 15 drops equals one milliliter and calculate the required delivery rate, or flow rate, to be 31 drops per minute. Therefore, based on experience, the nurse initially adjusts the wheel on the roller clamp to what his or her experience would be about the correct rate. The nurse then counts the drops delivered over 15 seconds, multiplies by four, and further adjusts the roller clamp to obtain the required flow rate . If all factors remain constant, this method will accurately deliver the prescribed medication.

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However, in this gravity-based IV setup, things do not remain constant, especially the flow rate . Patients turn in their bed, they move their arms, even their blood pressure changes—all of which affect the flow rate , which can result in under or over administration of the ordered solution. For critical medications, such as anticoagulants and analgesics, a better method must be employed to ensure that the flow rate is accurately maintained during the course of administration of the IV. That better method is the IV pump.

Current Technology

These days, IV pumps are used for those medications as well as for the delivery of epidural anesthetic agents, cardiovascular and chemotherapy drugs, blood, home IV therapy, and form the heart of patient-controlled analgesic units. An IV pump accurately delivers a pressurized stream of medication, up to about 14 psi as needed, regardless of patient movement, blood pressure changes, and sounds an alarm to alert nursing staff to problems such as its inability to deliver the IV solution as ordered. All IV pumps share certain commonalities regardless of how they move the fluid from the container to the patient or how many channels they have. One commonality across all manufacturers and models is their ability to operate using either an internal rechargeable battery or from a convenience outlet as their source of power.

All IV pumps employ one of three methods to move the fluid—either a linear or rotary peristaltic pumping mechanism, or a proprietary cassette mechanism. The linear mechanism, the most common peristaltic pumping mechanism, must only be used with U.S. Food and Drug Administration-approved IV administration sets. The approved set meets certain specifications, such as precise exterior and interior diameters and exact resiliency and stretch characteristics. Using an approved set ensures that the pump will deliver the fluid in the programmed amount at the correct rate. This is because the accuracy of the linear peristaltic pump relies on the parameters of the IV tubing. The pumping mechanism itself consists of a series of moveable disks, each one typically less than ¼ inches thick, stacked to a height of several inches, sequentially moving in a rippling or peristaltic motion, hence its name. Behind the stack is a rotating shaft (driven by a stepper motor) sequentially moving the

individual disks in a constant rippling motion. In front of the stack is a flat plate—most designs include this as part of an opening "door" enclosing the tubing. This rippling or "peristaltic" action sequentially occludes and compresses the tubing against the flat plate, moving the fluid down the tubing. As the peristaltic action forces fluid out of the tubing at the patient end, replacement fluid enters from the drip chamber. The rate that the pulses are provided to the stepper motor determines the speed of the rotating shaft, and that combined with the known diameter/volume of the tubing set determines the flow rate to the patient.

The designs of the rotary peristaltic, positive displacement, or roller pump versions are both standard and very basic. The rotary peristaltic pumping mechanism of a typical IV pump uses a length of silicone tubing, often part of a "special" IV tubing system, to move fluid from the liquid source to the patient. The silicone tubing is wrapped approximately three-quarters of the way around the external circumference of a roller pump. As the impeller rotates, the rollers (sometimes referred to as shoes, wipers, or lobes) both occlude and force the fluid down the tubing to the exit. Before the pushing roller clears the tubing, the roller on the opposite end of the impeller occludes the tubing just after the inlet and, with continued rotation of the impeller, now pushes the fluid toward the exit. As fluid leaves the tubing and enters the patient's vein, replacement fluid enters from the drip chamber. The speed of the impeller determines the flow rate in this design.

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The proprietary cassette mechanism design uses a special IV tubing set, often unavailable on the aftermarket. The cassette snaps or locks onto the IV pump and typically employs a syringe or piston-type device to deliver the fluid. The cassette has both inlet and outlet tubing sets, employing either one-way valves or a pump-operated valve assembly, to ensure the fluid flows in the right direction. The typical sequence of events of this mechanism is a simple two-step process. First, the valve assembly (if provided) switches to the inlet side and the pump quickly pulls the plunger or piston to fill the barrel mechanism. Second, the valve assembly switches to the outlet side and the pump slowly— virtually imperceptibly—pushes the plunger or piston to deliver the IV fluid to the patient. This process continues during the administration of the IV fluid. Both the speed at which this action takes place as well as the speed at which the plunger or piston moves determines the flow rate . One variant of this design uses a dual syringe or piston cassette that alternatively fills one while dispensing from the other. This design virtually eliminates any pause in administration of the IV fluid.

Independent of the mechanical design, all basic IV pumps share many of the same characteristics. Two features common to all modern pumps are an air-in-line and occlusion/highline pressure alarms. Manufacturers use different methods to sense these malfunctions from the simplest optical sensor and pressure transducer to esoteric proprietary designs. Another common feature is the programmability of the pump to deliver the IV at a particular rate, or to deliver a total volume, or both. Once the desired volume has been infused, most pumps will slow to a very low rate, around 3 mL/hour. This KVO (keep vein open) or TKO (to keep open) rate keeps a positive pressure in the tubing and fluid flowing to prevent the IV catheter from becoming clogged by a blood clot. Often, along with the IV rate dropping to a KVO rate, most pumps sound an audible alarm when the desired volume has been infused, or the IV source (bottle or bag) is empty. Pumps that are more expensive also contain alarms that sound if there is air in the IV line, excessive line pressure probably caused by an occlusion (blockage) of the tubing, a flow rate error, or disconnection of the IV tubing, and also maintain an onboard data log. The data log typically includes the date and time of user key presses, system error messages, alarm events, as well as pump settings. The data log usually is accessed via an Ethernet or RS-232 port, or even wirelessly in the most feature-laden models. All IV

Origin and Evolution

Across the continuum of the development of medical devices, the infusion pump is the relative teenager. The demand for some form of automated infusion system came from the "modern" operating rooms and intensive care units in hospitals during the 1950s. Healthcare providers needed a way of regulating the administration of fluids and blood products that was less labor intensive and more efficient then the process of the day. The existing technology required nursing staff to spend a good deal of their time giving injections, monitoring and manually adjusting the flow rate of intravenous solutions. For some of the newest medications, the normal method of administration was simply intolerable due to the narrow therapeutic range of the medication and the adverse results (uncontrollable hemorrhaging, for example) of the slightest over-infusion. This demand drove SigmaMotor, Inc., to develop, build, and start shipping the first infusion pumps in 1961.

By the mid-60s, after several redesigns, SigmaMotor had sold thousands of the new IV pumps and eventually dropped the word "Motor" from its name. By the 1970s, several other manufacturers entered the marketplace, including names we know today such as Alaris (formed by the merger of the IVAC and IMED companies and now under a larger entity called CareFusion), Baxter, Hospira, and Smiths Medical, for example. As pumps got more popular, engineers kept improving designs by adding innovative features such as power-up self-testing, on-board diagnostics, and organic memory to record events ranging from the nurse's programming keystrokes to alarm and battery usage history.

pumps operate from both AC (alternating current) line power and with internal batteries that can last for up to 12 hours.

Infusion pumps allow a secondary or "piggyback" IV to run concurrently, if using a multichannel pump, or consecutively, if using a single-channel pump, by connecting the piggyback IV to the injection port of the primary IV line. If using a multichannel pump, two (or more) pump channels work together to deliver the IV solutions as prescribed by the physician. For example, multichannel pumps can be programmed to deliver both solutions simultaneously at their programmed rates, or to fully infuse the piggyback IV first, then switch over to the primary IV solution. Multichannel pumps may share power supplies, and clock circuits, and employ a single common control panel. Other multichannel pumps are little more than two or more discreet IV pumps installed in a single housing.

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The top tier of IV pumps are loosely termed "smart pumps" because of their artificial intelligence–like abilities. These pumps contain computer technology and capabilities that allow them to provide pharmacist-like consultation within the pump. Smart pumps contain the hospital IV formulary, facility locations (such as ER, MICU, etc.), and dosing information for each medication in the formulary. To use a smart pump, the nurse interacts with the pump as if working with a pharmacist. The nurse typically selects the location, the medication, and may be prompted to enter the patient's age, weight, sex, etc., or the nurse may scan the patient's ID band and the Hospital Information System sends the required information to the IV pump. The nurse then selects the medication from a menu or scans a hospital-added label on the IV bag, and sets the infusion parameters and other information based upon IV pump prompts. The pump "knows" the normal or predetermined parameters for the medication and alerts the nurse if the set infusion rate, for example, exceeds those parameters. Depending on the pump's design and the severity of the alert, the nurse must either override the alert or change the unacceptable setting. During infusion, smart pumps generally display infusion information such as the name and concentration of the medication, flow rate , volume infused, remaining volume, etc. The formulary in the "brightest" smart pumps can be updated wirelessly, while standalone IV pumps must be individually located and updated, usually by connecting them to a laptop computer through a USB port.

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How to Manage Intravenous Pumps

A detailed maintenance history should be maintained for each pump supported, even if the actual maintenance is contracted out to either the manufacturer or a third party. The history should include all scheduled services and both modification and remediation work orders. All manufacturer recommended scheduled services should be performed and documented, especially calibration since this is one of the more critical aspects of the IV pump's function.

Regulations

There are no specific regulations covering intravenous pumps beyond the requirement to conform to the regulations promulgated by the FDA for sale and use of medical devices in the United States. Other authorities, such as the European Community, have similar requirements.

Risk Management Issues

Modern IV pumps are pretty much "bullet proof," and perform a wide array of self-checks during the power-up sequence. However, problems still can occur with ancillary items. For example, using the wrong size or type IV set may result in improper delivery of the prescribed solution. Even the correct tubing set can have problems that result in leaks. If the leak is downstream of the pump, the puddle will be obvious. But if the leak is between the IV fluid source and the pump, the potential

exists for a bubble to form in the IV tubing. This bubble may go undetected and be administered to the patient. This can have fatal consequences. The cassette or cartridge assembly used in some pump designs may also develop leaks at their connections, with the same potential outcomes.

Additional risk management issues can be the result of staff errors. This is an area where the smart pump technology can assist in mitigation and staff training. Pharmacy personnel may make a mistake when programming the pump with the IV formulary, or the nursing staff may improperly enter the parameters of the infusion order into the IV pump. Nursing staff improperly overriding the alerts provided by smart pumps could cause an overdose and a potentially fatal consequence. The ability to download pump events through either the USB port or wirelessly can shed light on these errors and can be an indicator that focused staff training is required. Accidental overinfusion also can occur if an old IV set, lacking free-flow protection, is used, or if the tubing's free-flow protection is removed prematurely.

Finally, a pump inadvertently set to be too sensitive to infiltration, obstruction, or high back pressure (such as a pump configured for pediatric use inadvertently used on an adult ward) will contribute to alarm fatigue in the staff and wasted nursing resources silencing these false alarms. A pump that is set up for use on normal patients can damage the vein if it fails to sense the increased back pressure (and stop pumping and alarm) when the IV of a pediatric or geriatric patient becomes infiltrated.

Troubleshooting

As alluded to, modern IV pumps are virtually failure free, or they detect a problem and refuse to operate. Typically, the repairer will place the pump into a maintenance mode to determine, usually by error code, the nature of the malfunction. The repairer will also usually take the opportunity to examine the internal error and activity logs in an attempt to gain further insight into the cause of the current problem. Of course, as with other battery-powered equipment, batteries are always going to require some form of servicing, load testing, etc.

Training and Equipment

A basic biomedical equipment tool kit that includes a good digital multimeter (DMM) is necessary to perform very basic service of IV pumps. Additionally, an IV pump analyzer will allow the service technician to perform calibration more efficiently. This equipment will facilitate most of the services an IV pump requires. For more in-depth troubleshooting of hard failures, manufacturers' training coupled with good manufacturers' service literature providing both service information and parts lists is a must-have item. Some pumps require the use of alignment jigs after replacing the pumping mechanism, while other manufacturers claim that this service is too complicated for the in-house biomed to handle. These manufacturers will either refuse to sell parts to in-house maintainers or make repair parts sales contingent upon the receipt of expensive manufacturer's training. Therefore, the only viable alternative is to have the pump serviced only at the manufacturer's facility.

Future Development

The mechanisms of the IV pump, which have been around for more than 40 years, are considered mature technology. However, the electronics side is ever evolving. The earliest pumps needed a device to count the drops and only alarmed if the set infusion rate could not be achieved. Nowadays, only about half the pumps on the market employ drop sensors. The next major advancement in IV pump technology is the addition of bar-code readers and their associated wireless technology that will ensure the IV solution, the flow rate , and the patient to whom it is administered, are exactly as the physician ordered. ■

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