BRIEF REVIEW OF DIFFERENT TYPES OF PARENTRAL DEVICES

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ABSTRACT

The term parenteral is applied to preparations administered by injection through one or more layer of skin tissue. The word parenteral is derived from Greek word Para and Enteron, meaning outside of intestine, and is used for dosage forms administered by routes other than oral route. Parenteral dosage forms differ from all other drug dosage forms because they are injected directly into body tissue through the primary protective system of the human body, the skin and mucous membranes. The Federal Food, Drug and Cosmetic Act defines the term "Devices" as instruments, apparatus and contrivances, including their components, parts and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or to affect the structure or any function of the body of man or other animals. The term "Parenteral Devices" is used for the equipments needed for the administration of parenteral drugs. Also Devise can be defined as an instrument, apparatus, implement, machine, implant, invitro reagent or other similar or related article, including any component part or accessory which is recognized in the official formulary or the USP or any supplement to them, Intended for use in the diagnosis of disease or other condition or in the cure, mitigation, treatment or prevention of the disease in man or other animals or Intended to affect the structure or any functions of the body of the man or other animals and which does not achieve its primary intended purpose through chemical action within or on the body of man or other animal and which is not dependent upon being metabolized for the achievement of its primary intended purpose.

KEYWORDS Routes of administration, types of parenteral devices, sterilization of devices.

INTRODUCTION

The Federal Food, Drug and Cosmetic Act defines the term "Devices" as instruments, apparatus and contrivances, including their components, parts and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or to affect the structure or any function of the body of man or other animals. The term "Parenteral Devices" is used for the equipments needed for the administration of parenteral drugs. These devices include syringes and cannulas. These devices must be sterile, pyrogen-free and free from particulate matter[1]. Also Devise can be defined as an instrument, apparatus, implement, machine, implant, invitro reagent or other similar or related article, including any component part or accessory which is

- Recognized in the official formulary or the USP or any supplement to them.
- Intended for use in the diagnosis of disease or other condition or in the cure, mitigation, treatment or prevention of the disease in man or other animals or
- Intended to affect the structure or any functions of the body of the man or other animals and which does not achieve its primary intended purpose through chemical action within or on the body of man or other animal and which is not dependent upon being metabolized for the achievement of its primary intended purpose[2].

The word parenteral is derived from Greek word Para and Enteron, meaning outside of intestine, and is used for dosage forms administered by routes other than oral route. Parenteral dosage forms differ from all other drug dosage forms because they are injected directly into body tissue through the primary protective system of the human body, the skin and mucous membranes. They must be exceptionally pure and free from Physical, chemical and biological contaminants. These requirements place a heavy responsibility on the pharmaceutical industry to practice current good manufacturing practices in the manufacture of parenteral dosage forms and medical devices[3].

ROUTES OF ADMINISTRATION

Drugs may be injected into almost any organ or area of the body, including the joints (intra-particular), joint fluid area (intrasynovial), spinal column (intraspinal), spinal fluid (intrathecal), arteries (intra-arterial), and in an emergency, even the heart (intracardiac). However, most injections go into a vein (intravenous, IV), into a muscle (intramuscular, IM), into the skin (intradermal, ID, intracutaneous), or under the skin (subcutaneous,

SC)[4]. Intravenous drugs provide rapid action compared with other routes of administration and because drug absorption is not a factor, optimum blood levels may be achieved with accuracy and immediacy not possible by other routes[5]. In emergencies intravenous administration of a drug may be lifesaving because of the placement of the drug directly into the circulation and the prompt action that ensues. Intramuscular injections of drugs provide effects that are less rapid but generally longer lasting than those obtained from intravenous administration. The subcutaneous route may be used for injection of small amounts of medication. The usual site for intradermal injection is anterior forearm. The needle is inserted horizontally into the skin with the bevel facing up for intradermal administration[3].

TYPES OF PARENTERAL DEVICES

Syringe Syringes and needles are sterile devices used to inject solutions into or withdraw secretions from the body. The syringe is a calibrated glass or plastic cylinder with a plunger at one and an opening to which the needle attaches. The word "syringe" is derived from the Greek syrinx = "tube" via back-formation of a new singular from its Greek-type plural "syringes"[6]. There are different types and sizes of syringes used for a variety of purposes. Syringe sizes may vary from 0.25 ml to 450 ml, and can be made from glass or assorted plastics.

- Luer-lock tip: -this kind of tip is stronger than a regular tip which locks the needle onto the nozzle of the syringe. The threads of the Luer lock tip of this 12 ml disposable syringe keeps it securely connected to a tube or other apparatus. It cannot pop off accidentally.
- Slip tip: - slip needle do not lock in place which secures the needle by compressing the hub onto the syringe nozzle. They have the disadvantage of sometime allowing the needle to pop off from the pressure of injection.
- Eccentric tip:-This infrequently used tip is designed off center for use when the needle is to be kept as nearly parallel to the field of injection as possible which secures with a connection that is almost flush with the side of the syringe[7].

Examples: - medical syringe, insulin syringe, disposable syringe & tuberculin syringe

Needles Needles is a slender, sharply pointed instrument or devise used for suturing, ligaturing or puncturing, removal of material from a clinically or rediologically identified mass by aspirating it through hollow needle attached to a syringe[7]. Needles are almost always disposable, but reusable ones are available for home use by a single patient. The diameter of the needle is indicated by the needle gauge. Various needle lengths are available for any given gauge. There are a number of systems for gauging needles, including the Stubs Needle Gauge, and the French Catheter Scale. Needles in common medical use range from 7 gauge (the largest) to 33 (the smallest) on the Stubs scale. Twenty-one-gauge needles are most commonly used for drawing blood for testing purposes, and sixteen- or seventeen-gauge needles are most commonly used for blood donation, as they are large enough to allow red blood cells to pass through the needle without rupturing (this also allows more blood to be collected in a shorter time). Larger-gauge needles (with smaller diameter) will rupture the red blood cells, and if this occurs, the blood is useless for the patient receiving it. Although reusable needles remain useful for some scientific applications, disposable needles are far more common in medicine. Disposable needles are embedded in a plastic or aluminium hub that attaches to the syringe barrel by means of a press-fit or twist-on fitting.[7]

Examples: - hypodermic needles, winged needles.

Cannulae A cannula (from Latin "little reed"; plural cannulae) or cannula is a tube that can be inserted into the body, often for the delivery or removal of fluid. Cannulae normally come with a trocar attached, which allows puncturing of the body in order to get into the intended space. There are, however, 11 different kinds of cannulae: Bias Grind, Vet Point, Lancet Point, Deflected point (Anti-Coring), Pencil Point, Closed-End Consistent Wall, Welded "Ball" End, Bullet Point, Razor Edge, Probe Point (Blunt End), and Trocar. Intravenous cannulae are the most common in hospital use. A variety of cannulae are used to establish cardiopulmonary bypass in cardiac surgery. Nasal cannula is a piece of plastic tubing that runs under the nose and is used to administer oxygen[8].

Examples:- Intravenous (IV) cannulation & Nasal cannulation.

Catheter In medicine a catheter is a tube that can be inserted into a body cavity, duct or vessel. Catheters thereby allow drainage, injection of fluids or access by surgical instruments. The process of inserting a catheter is catheterization. In most uses a catheter is a thin, flexible tube ("soft" catheter), although in some uses it is a larger, solid tube ("hard" catheter). A catheter left inside the body, either temporarily or permanently, may be referred to as an indwelling catheter. A permanently inserted catheter may be referred to as a permcath[9]. The word "katheter" in turn came from "kathiemai" meaning "to sound" with a probe. The ancient Greeks inserted a hollow metal tube through the urethra into the bladder to empty it and the tube came to be known as a "katheter"[9].The French catheter scale or "French units" (Fr) is commonly used to measure the outside diameter of needles, catheters, and other cylindrical medical instruments.1 Fr is equivalent to 0.33 mm = .013" = 1/77" of diameter. Thus, the size in French units is roughly equal to the circumference of the catheter in millimeters.

Examples:- Arterial catheter, Balloon catheter, Cardiac catheterization, Central venous catheter, Dialysis catheter, Foley catheter, Peripheral venous catheter, Pulmonary artery catheter, Urinary catheters

Infusion set The infusion set is most commonly used to administer fluids from an intravenous container by gravity. The more basic sets are found to contain a bottle or bag piercing pin, a sight chamber to allow the counting of drops, tubing somewhere in the neighborhood of 0.100 inch internal diameter, a flow control clamp, a 'Y' reseal to allow emergency entry and male needle adaptor to connect to the vanipuncture device. Most manufacturer have standardized on set length between 75-79 inch. The container must be supported above the patient in order for the solution to flow. The inverted container with the administration set in place is hung approximately 1 meter above the patient. Flow will not begin until the pinch clamp is opened and air is allowed to enter the container. As the solution leaves the container, it drops into a drip chamber (sight chamber). By collecting in this chamber, the solution can flow without allowing air to enter the length of administration tubing. The rate can be adjusted by counting the drop that enters the drip chamber. The clamp is then adjusted to regulate flow. The stain less steel cannulas are used for I.V administration, an 18-21 gauge needle is commonly used.

Advantages:

- Provide accurate and timely delivery of fluids and drugs.
- Can change the flow rate when needed.
- Provide controlled limitation of fluid intake.
- Reduce infiltration rate.
- Reduce the cost of I.V. therapy.

Uses:

- Use for total parenteral nutrition.
- Use for blood and blood product.
- Use for continuous drug therapy.
- Use for peritoneal dialysis.
- Use for closed wound irrigation.
- Use for insulin therapy.

Feeding tube A feeding tube is a medical device used to provide nutrition to patients who cannot obtain nutrition by swallowing. The state of being fed by a feeding tube is called enteral feeding or tube feeding. Placement may be temporary for the treatment of acute conditions or lifelong in the case of chronic disabilities. A variety of feeding tubes are used in medical practice. They are usually made of polyurethane or silicone. The diameter of a feeding tube is measured in French units (each French unit equals 0.33 millimeters). They are classified by site of insertion and intended use[10].

Examples:- nasogastric & gastric feeding tube

Stents In medicine, a stent is a man-made 'tube' inserted into a natural passage/conduit in the body to prevent, or counteract, a disease-induced, localized flow constriction. The term may also refer to a tube used to temporarily hold such a natural conduit open to allow access for surgery. A stent is a wire metal mesh tube used to prop open an artery during angioplasty. The stent is collapsed to a small diameter and put over a balloon catheter. It's then moved into the area of the blockage. When the balloon is inflated, the stent expands, locks in place and forms a scaffold. This holds the artery open. The stent stays in the artery permanently, holds it open, improves blood flow to the heart muscle and relieves symptoms (usually chest pain). Within a few weeks of the time the stent was placed, the inside lining of the artery (the endothelium) grows over the metal surface of the stent[14] Stents are used depending on certain features of the artery blockage. This includes the size of the artery and where the blockage is. Stenting is a fairly common procedure; in fact, over 70 percent of coronary angioplasty procedures also include stenting.[11]

Examples: - drug-eluting stents

Injection port An injection port is a medical device used for the administration of insulin or other physician approved medicine into the subcutaneous tissue (the tissue layer just below the skin). The device is similar to infusion sets used by insulin pumps, except it is configured to receive a syringe instead of a tubing system. An injection port is usually a disposable device applied by the patient and worn for period of 3-5 days. When giving shots via an injection port, the needle stays above the surface of the skin. Medication is delivered via a short, soft cannula. An injection port can be used in conjunction in the with multiple daily injections of insulin by people with diabetes. It can also be used for the subcutaneous administration of any other physician prescribed medication[9]. Injection ports are usually applied by the patient. The device comes with a needle surrounded by a soft cannula. The needle and cannula are manually inserted into the patient's tissue. Immediately after insertion the needle is removed and the cannula remains below the surface of the skin. Ports are usually worn on the

abdomen, but can also be worn on other areas such as the buttocks, thigh or arm. Typical injection ports are worn for 3-5 days and then replaced with another port. Insulin is injected via a syringe into the injection port. Medication immediately flows through the device's cannula into the subcutaneous tissue layer. No medication is stored in the device (other than the small amount of dead-space in the medication channel within the device)[12.]

Advantages of Injection Ports

- Reduces skin punctures
- Reduces fear and anxiety associated with multiple daily injections.
- Reduces bruising around injection site
- No need to wear an insulin pump
- Viable alternative to standard injections

Disadvantages of Injection Ports

- Injection ports must be obtained in addition to syringes and medication.
- Ports are sometimes not covered by insurance.
- Patient still has to administer shots.

STERILIZATION

Sterilization is a process by which all viable microorganisms are removed or destroyed, based on a probability function.[13] Sterilization is the elimination of all transmissible agents from a surface, a piece of equipment, food or biological culture medium. This is different from disinfections, where only organisms that can cause disease are removed by a disinfectant. In general, any instrument that enters an already sterile part of the body should be sterilized. This includes equipment like scalpels, hypodermic needles. Autoclaving is the most common method of sterilization. While there are some plastic devise which would not remain dimensionally stable under autoclave temperature are sterilized by other method like gas sterilized (ethylene oxide) or by radiation sterilization (gamma beam).

Autoclave sterilization Typically to sterilize by autoclave a pressurized steam autoclave operates at 121ºc for at least 15 min.

Radiation sterilization This method is effective for medical devices. That can withstand the attack of gamma bombardment. It is specially useful for the polymers that are sensitive to heat moisture or ethylene oxide.

Gas sterilization Ethylene oxide is widely used as sterilant and is harmless to most plastics. Ethylene oxide sterilization is used for most of the plastic syringe and needle[2].

REFERENCES

[1] Ansel HC., Allen LV, Pharmaceutical Dosage Form & drug delivery systems, Parenterals: 399
[2] Lachman L,. Lieberman H, Pharmaceutical Dosage Forms: Parenteral Medications, Marcel Dekker, 2nd Edition, Vol 3, Medical Devices: 425, 487
[3] Turco SJ, Sterile Dosage Forms, their preparation and clinical application, 4thEdition, Devices: 318-335.
[4] Pawar A, Gaud RS., Modern Dispensing Pharmacy, career publication, 2nd Edition, Sterile Products: 360-361
[5] Jain N.K., Pharmaceutical Product Development, Routes of Administration of Parenterals: 139-140
[6] http://en.wikipedia.org/wiki/Syringe
[7] http ://www.answers.com/topic/syringe-and-needle
[8] http://en.wikipedia.org/wiki/cannulas
[9] http://en.wikipedia.org/wiki/catheter
[10] http://en.wikipedia.org/wiki/Feeding_tube
[11] http://en.wikipedia.org/wiki/Stent
[12] http://en.wikipedia.org/wiki/injectionport
[13] Remington, The Science & Practice of Pharmacy, 20th Edition, Vol I, Sterilization: 753.

LIST OF FIGURES

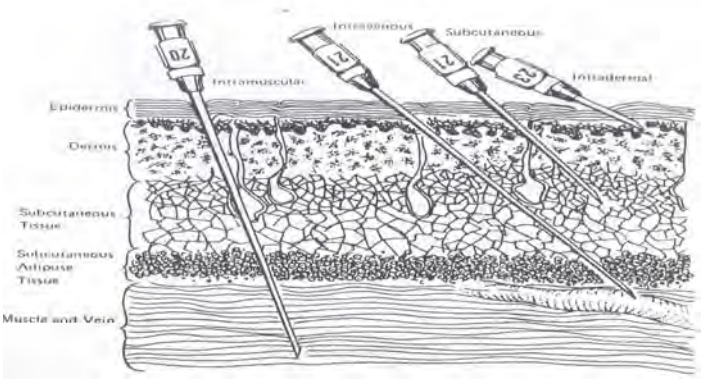

Fig 1: Routes of parenteral administration.

Fig 2: Syringe

Fig 3: Luer-lock tip Syringe

Fig 4: Slip tip Syringe

Fig 5: Eccentric Syringe tip

Fig 6: Needle

Fig 7: Hypodermic needle

Fig 8: Winged needle

Fig 9: Intravenous cannulation.

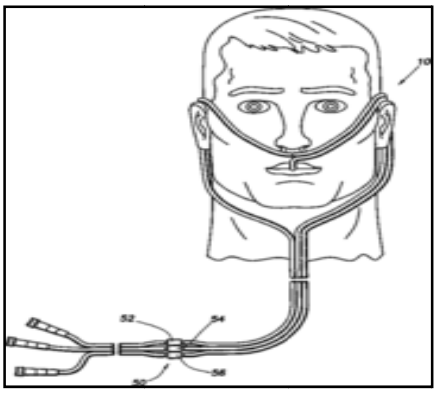

Fig 10: Nasal cannulation.

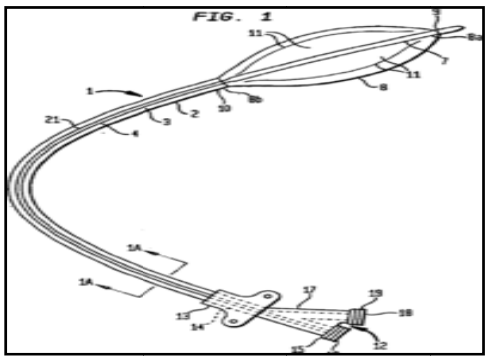

Fig 11: Balloon Catheter

Fig 12: Foley catheter

Fig 13: Peripheral venous catheter

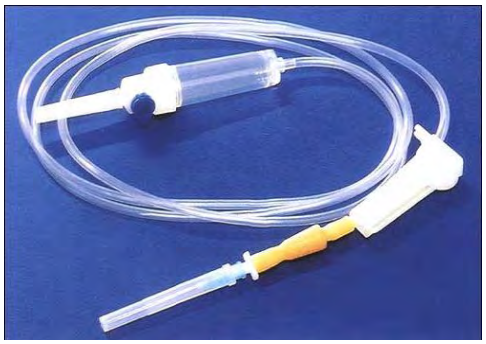

Fig 14: Infusion set

Fig 15: Feeding tube

Fig 16: Stent

Fig 17: JET INJECTOR

LIST OF TABLES

Table 1: Routes and administration volume of drug

Sr. No.	ROUTE	Volume (drug)	DESCRIPTION
1	Intramuscular	Up to 2 ml in Deltoid muscle	Directly into the body of a relaxed muscle.
2	Intravenous	0.5 ml to 1 Litre	Directly into a vein.
3	Subcutaneous	Max. Up to 1 ml	Into the loose connective and adipose tissue beneath the skin.
4	Intra-arterial	Up to 20 ml	Into an artery which leads directly to the target organ.
5	Intra-articular	Up to 20 ml	Into synovial sacs of various accessible joints.
6	Intra- cardiac	Up to 20 ml	Directly into chambers of the heart.
7	Intradermal	Max up to 0.2 ml, usual 0.1ml	Into the dermis located just beneath and adjacent to the epidermis.
8	Intraocular a. Anterior chamber b. Subconjunctival	Not exuding 1 ml	Directly into the anterior chamber of the eye. Injections are given beneath the conjunctiva.

Table 2: Needle Selection

Sr No.	Injection Site	Length Range (inch.)	Gauge Range
1	Intradermal	1/4 to 5/8	24 to 26
2	Subcutaneous	1/4 to 5/8	24 to 25
3	Intramuscular	1 to 2	19 to 22
4	Intravenous Metal needle Winged needle Plastic needle Intracatheter	 1 to 2 3 /4 to 1 ½ 3 to 5 11	 15 to 25 16 to 23 15 to 21 15 to 21
5	Intra-articulate	1 to 3	19 to 22
6	Intraperitonial	4 to 6	14
7	Intramyocardial	3	18 to 21
8	Intrathoracic	5 to 6	13
9	Intraspinal Adult Pediatric Neonatal	 3 to 5 1 to 2 ½ to 1	 20 to 22 25 27