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A New Generation of Pulsatile Infusion Devices

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ABSTRACT

A selection of pulsatile infusion devices suitable for administering LHRH are described. The principles of operation and control options of the different pumps are explained, including the new compact direct-drive syringe pump. The relative merits of these infusion systems are discussed and it is concluded that size, ease of use and range of application are paramount.

INTRODUCTION

The mid-seventies saw the start of continuous insulin infusion therapy. One of the first commercial pumps available, the Mill Hill Infuser (2), is still used today. Although very simple, it forms the basis of many of the current infuser designs. The latest insulin infusers incorporate many additional features not present in the early models, such as variable flow rates and multiple alarms, making them easier and safer to use.

A whole new generation of pumps, capable of an intermittent mode of delivery, began to appear with the introduction of pulsatile LHRH therapy. A selection of these are described below.

DESCRIPTION

Drive Principles

There are three types of drive principle in common use: roller peristaltic, leadscrew and direct drive.

A peristaltic pump uses a disposable bag and silicone outlet tube. The tube is stretched round the roller mechanism and, as the roller turns, the contents of the tube are expelled from the cannula. This type of drive is compact but the reservoir requires careful filling to avoid air inclusion. One of the first pumps used for LHRH therapy was the Zyklomat roller

peristaltic pump (Ferring). This pump was specifically designed for a fixed concentration of LHRH and as such only has one bolus volume and time interval.

The principle of the leadscrew drive is shown in Figure 1a. The motor drives the leadscrew through a reduction gearbox. Rotary motion of the leadscrew is transferred via a carriage assembly to linear movement thus driving the syringe plunger. This mechanism, although simple, has many drawbacks. Before a new syringe is loaded, the carriage assembly has to be returned to its start position either by reversing the drive or by temporarily disconnecting the carriage assembly. Once loaded, any gaps between the syringe and the carriage, and any backlash in the gears have to be removed by a lengthy priming process. The size of this drive system makes the currently available leadscrew devices extremely large.

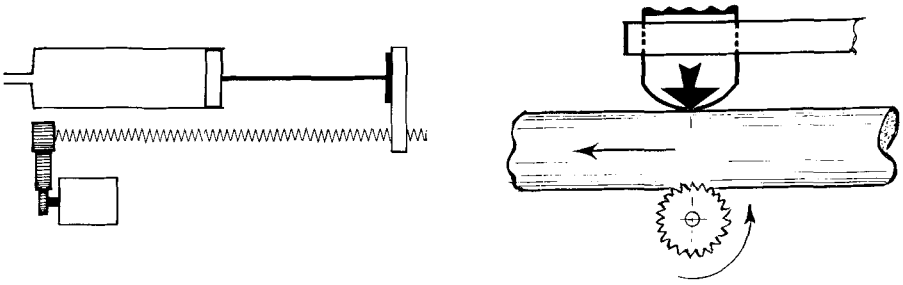

Fig 1: Drive principle of a) leadscrew and b) direct drive.

The direct drive principle (1,3), shown in Figure 1b, is similar to a rack and pinion. The drive is transmitted directly to the cylindrical plunger of the syringe (the rack) by means of a serrated or splined roller (the pinion) which forms teeth in the plastic plunger as it turns. The advantages of this drive system are its compact size, freedom from backlash and ease of loading the syringe assembly).

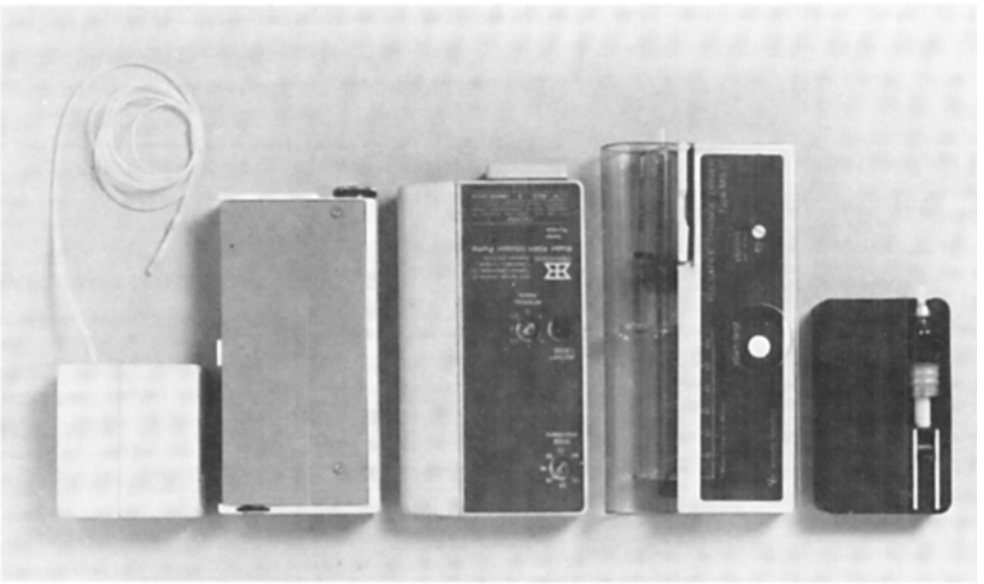

Fig 2: Infusers used for the pulsatile administration of LHRH.

Fig 2 shows a selection of infusers which have been used for the pulsatile administration of LHRH. From left to right, they are the Zyklomat, Mill Hill (modified by Blows), Autosyringe/Travenol, Graseby MS 27 and the NIMR (General Purpose).

Control

The pumps described give a series of microinjections of a preset bolus size and time interval, with ranges as shown in Figure 3. A wide choice of clinical applications is possible if a versatile range is chosen.

Most of the pumps have a selection of time intervals, apart from the Zyklomat that has been designed specifically for LHRH infusion with a time interval of 90 minutes. The range of the Graseby pump is divided down by integer values from 3 hours. Consequently it has a large gap between 1.5 and 3 hours and a somewhat condensed scale at the low end of the range.

Only the Autosyringe and NIMR (General Purpose) have a selection of bolus volumes. Both the Graseby and the Zyklomat have a fixed bolus volume of about 60 microlitres and vary the dose by dilution, and in the case of the Graseby, by varying the syringe size. The modified Mill Hill has two bolus volumes but otherwise relies on dilution of the infused fluid.

Flow is monitored by a switch detecting leadscrew rotation in the Autosyringe and the Graseby pumps, an LED/Photo-transistor detecting gear wheel rotation in the NIMR (General Purpose) and by a fixed time period in

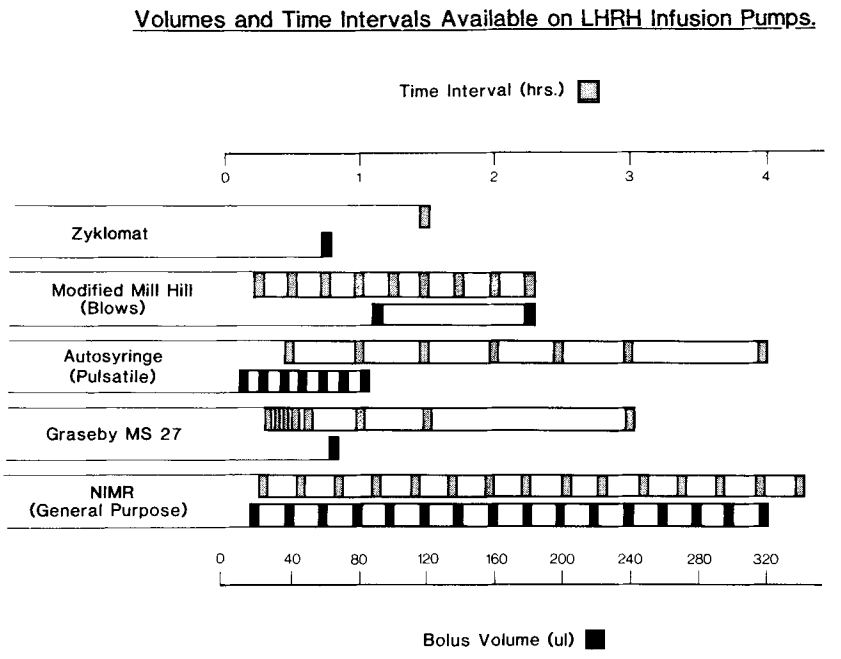

Fig. 3: Volumes and time intervals available on LHRH infusion pumps.

the Zyklomat. While the flow performance of all the syringe pumps was measured to be within $\pm$10%, the Zyklomat gave a significant underdelivery at low battery voltage.

DISCUSSION

The requirements of the clinician and the preference of the patient are important parameters when considering the design of a new infuser.

The clinician requires a device which is versatile enough to meet his changing needs, and simple enough to avoid lengthy training sessions on the use of the pump. The availability of prefilled syringes or reservoirs not only simplifies use and reduces the risk of infection, but avoids aeration of the infusate and subsequent flow errors due to the thermal expansion of entrapped air.

The patient requires a device which is small, so that it can be inconspicuously concealed on the body avoiding any embarrassment in public. They also prefer prefilled reservoirs as they are easy to change and require less equipment.

Of the pumps described above only the NIMR (General Purpose) and the Zyclomat are small enough to fulfil the patient size requirement, although the thickness of the Zyklomat can be obtrusive. While the Zyklomat is suitable for LHRH therapy, it does not have the versatility required by most clinicians.

As pulsatile hormone therapy is still in its infancy, both the dosage and frequency for optimum control are bound to change with time. In the future, therefore, devices will become even smaller and slimmer, with a wide choice of flow regimes. Drugs will inevitably become more concentrated making flow accuracy an important and critical requirement.

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