

Study of Key Commodity Aspects of Injection Pens for Insulin Administration and Needles for Them

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Abstract

Introduction: Diabetes mellitus is a disease which is the most common cause of early disability and high mortality. One of the most effective treatments for diabetes is insulin therapy. The treatment is carried out using different types of insulin produced by the pharmaceutical industry. However, any such preparations are always a solution, which must be introduced with a device. **Materials and Methods:** Analysis of the State Register of medical equipment and medical products: Injection pens for insulin and needles for them of different brands that are most used to treat diabetes patients. **Results and Discussion:** Today on the world market, there are numerous devices that are used to deliver insulin into the body, including the special syringes, insulin pumps, injection pens, and more. Today, such a device as injection pen (autoinjector) is the most convenient for insulin administration. In the Ukrainian market, there are syringe-pens of mostly foreign origin. **Conclusion:** Use can increase compliance that increases the acceptability of treatment (ease of use, less pain) and improve blood glucose control.

Key words: Diabetes, insulin, insulin therapy syringe pen, injections, needles for injection pens

INTRODUCTION

Insulin is a hormone that is actively involved in human metabolism. Normally, it is produced in the pancreas and enters the bloodstream. The main effect of insulin is to reduce blood sugar. If this hormone is no longer produced or function normally in the body, diabetes develops. Diabetes is a disease which is the most common cause of early disability and high mortality. Now, there are over 287 million diabetes patients worldwide^[1-3] and by 2030 experts foresee an increase in that figure to 438.4 million people.^[3-6]

In 1921, Canadian doctors Frederick Grant Banting and Charles Herbert Best first received an extract from the pancreas of dogs, which eliminated glucosuria and hyperglycemia in diabetic patients. A year later, the first commercial insulin preparations from purified extract of the pancreas have been prepared, and in 1923 with the discovery of insulin and banting and best were awarded the Nobel Prize.

Insulin administration required special syringes that allow accurately dosing the drug and ensure its introduction in the subcutaneous fatty tissue.

In 1924, the company “Becton Dickinson” produces the world’s first syringe for insulin administration. Today several ways of insulin administration are used, using disposable syringes, syringe pens (in 1985 has been developed a reusable injection pen for insulin in 1989 - A disposable pre-filled syringe pen), and insulin dispensers (pumps).^[7]

The purpose of the study was to analyze the range and basic commodity characteristics (properties) of injection pens for insulin administration and needles for them in today’s market.

MATERIALS AND METHODS

Analysis of the state register of medical equipment and medical products: Injection pens for insulin and needles for them of different brands that are most used to treat diabetes patients.

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RESULTS AND DISCUSSION

Treatment of diabetes mellitus may include the introduction of different drugs in different modes and during treatment dose adjustment may be required. The need to reduce the human factor influence at medicines injection and to increase the acceptability of treatment for patients in different areas of medicine has led to the creation of special injection devices.

Devices for injections based on syringes and cartridges for self-administration of drugs exist on the world market for more than 10 years. Medical injection systems for self-administration are applied to treat infertility, diabetes, chronic diseases, and oncology. There are systems for injectable drug administration in daily and weekly dosage. Requirements to syringe pens and methods of testing thereof are established in international standard EN ISO 11608-1:2012.^[8] Modern injection systems are created following all the safety and efficiency requirements to high-tech materials from which they are made, preparations introduced, and are driven by the needs of the patient.

The world's largest experience in the use of injection devices is obtained in self-administration of insulin by diabetes patients. Today autoinjectors are most convenient for insulin administration. Their use can increase compliance, that is, the acceptability of treatment (ease of use, less expressed pain sensations) and improve control of blood glucose.^[9-13]

Autoinjector is an injector, through which subcutaneous administration of different types of insulin in diabetes is done. Today two types of syringe pens for self-introduction are used:

1. Disposable ready to use injection device containing solution [Figure 1];
2. Multiple use autoinjector with replaceable cartridges.

Injection procedure is as follows: The cap from the needle is removed, the skin is pierced with needle at the injection site, and completely until it stops input button is pressed. Due to the controlled speed of injection and fine needle, the pain is minimal.

The main advantages of injection pens

Minimal discomfort; A more exact dosage of insulin and thinner needle than using insulin syringes; patients who have low vision can set the dose not visually but with a click of the dosing device; cartridge of a syringe-pen is compact but roomy, its content is enough for 2-3 days.

According to the State Register of medical equipment and medical products, in the pharmaceutical market of Ukraine, there are mostly autoinjectors of foreign manufacturers, their share is 86%, and the share of domestic producers is only - 14%. Leading manufacturers of injection pens are

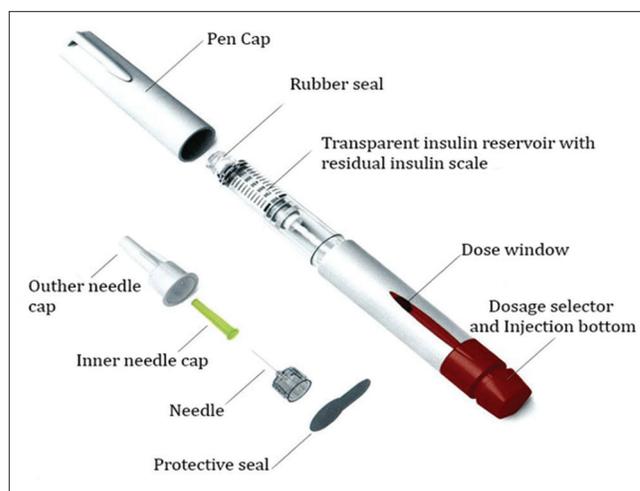


Figure 1: Design of syringe - pen

Germany and Denmark - 58%. A well-known domestic manufacturer of injection pens for insulin administration is leading Ukrainian producer of insulin Joint-Stock Company "Indar" (Kiev) [Table 1].^[14]

Results of the study have shown that in the domestic pharmaceutical market there are injection pens for insulin of mainly foreign production. Insulin syringe pens from various manufacturers and trade names differ in a number of consumer characteristics, but all manufacturers of insulin injectors keep defaults on the part of the device, which carries a needle. International Standard ISO 11608-2:12 "Needle-based injection systems for medical use - Requirements and test methods" imposes strict requirements to needles for insulin injectors as for their sterility, sharpening quality, flow rate, coating, and so on. All needles produced according to the ISO standards, have a universal thread and are compatible with different brands of insulin injectors (use of needles that are incompatible with the autoinjector can lead to leakage of insulin).^[15] The use of injection pens makes insulin injections more convenient compared to using insulin syringes which promote better adherence of insulin administration schedule and increases patient compliance.^[16]

The main parameters to choose needles for syringe pens are their size, length, and diameter. However, choosing needles for syringe-pens in each case requires a highly individual approach. It is important to note that the length of a needle is its functional characteristics and the diameter determines its consumer characteristics. That is why the modern classification of needles for insulin injectors includes the length of the needle.^[17] In accordance with this parameter needles for insulin, injectors are divided into three groups: Short (4-5 mm), medium (6-8 mm), and long (more than 8 mm) [Table 2].

As shown in Table 2, now the length of needles for insulin injectors varies from 4 to 12.7 mm. The first hypodermic needles were 16 mm in length, which often led to the drug

Table 1: The range of injection pens for insulin, according to the State Register of medical equipment and medical devices

Product name	Manufacturer
Insulin Autoinjector NovoPen Echo	Novo Nordisk A/S (Denmark)
Insulin Autoinjector NovoPen®4	Novo Nordisk A/S (Denmark)
Insulin Autoinjector id Pen TC U 32.5-21680915-002:2015	Private Joint Stock Company in the production of insulins "Indar" Ukraine
Reusable insulin autoinjector INSUPen	Biocon Limited (India)
Reusable autoinjector AllStar™	Sanofi-Aventis Deutschland GmbH, Germany
Automatic pen insulin injector "Gensupen"	Copernicus Sp. z oo, Poland
Reusable autoinjector for insulin cartridges (SmartPen)	Haselmeier GmbH (Germany)

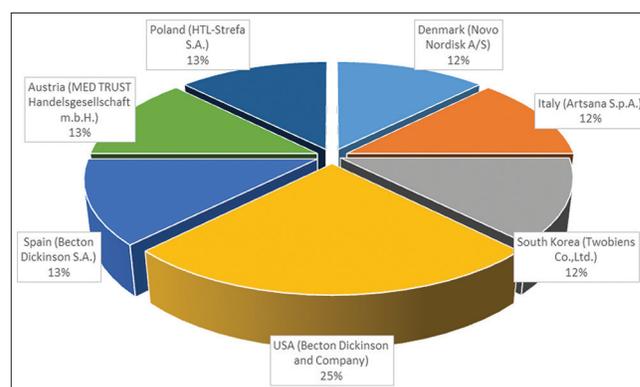
Table 2: Classification of needles for syringe-pens depending on the size

Size (length×diameter, mm)	Marking (G×mm)	Name, Manufacturer
Short		
4×0.23	32×4	Micro-Fine Plus "Becton Dickinson;" Insupen "Artsana"
5×0.25	31×5	Micro-Fine Plus "Becton Dickinson;" Insupen "Artsana"
5×0.23	32×5	NovoTwist, "Novo Nordisk"
Medium		
6×0.25	31×6	NovoFine "Novo Nordisk;" Unifine "Owen Mumford;" Insupen "Artsana"
8×0.30	30×8	Micro-Fine Plus "Becton Dickinson;" Insupen "Artsana;" NovoFine "Novo Nordisk"
8×0.25	31×8	Unifine "Owen Mumford;" PenFine "Ypsomed"
8×0.23	32×8	NovoTwist "Novo Nordisk;" Insupen "Artsana"
Long		
10×0.033	29×10	PenFine "Ypsomed"
12×0.033	29×12	PenFine "Ypsomed;" Insupen, "Artsana;" Unifine, "Owen Mumford"
12.7×0.033	29×12.7	Micro-Fine Plus, "Becton Dickinson"

administration in muscles and changed its characteristics (pharmacodynamics/pharmacokinetics). Creation of shorter needles (12.7 mm) has reduced the frequency of hypoglycemic states in adults with obesity but kept a high risk of such conditions in patients with deficiency of weight and children.^[18,19] Approximately, the same results were obtained when using 8 mm long needles.^[20] The frequent development of hypoglycemic reactions gave rise to the creation of shorter needles of length 5 and 4 mm.^[7]

The indicating diameter of insulin needles uses two systems of notation: Sheer (in mm) and relative (in arbitrary units - G). The higher is the number of G; the thinner is the needle. Each value of the needle diameter in G corresponds to a certain size in millimeters. For example, 29 G needle corresponds the diameter of 0.33, 30 G - 0.30, 31 G - 0.25, 32 G - 0.23 mm.

A segment of the domestic pharmaceutical market of needles for insulin injection pens consists entirely of products of

**Figure 2:** Structure of needles for insulin injection pens market by country of origin

only foreign production, according to the State Register of medical equipment and medical devices, namely seven foreign manufacturers supply their products to Ukraine [Figure 2] [14].

CONCLUSIONS

It is recognized that the diabetes disease carries with it a physical, psychological, and emotional strain on insulin-dependent patients. There is a need for medical devices for the treatment, which would reduce the burden associated with injections and overall experiences of patients. It is important that devices for insulin administration to be adapted for the most convenient and safe operation, and patients were confident in the accuracy of the dose administered. Such a device as autoinjector has a nice color and thoughtful design that understandable to any patient. This device allows controlling and modifying the dosage of the drug, makes the injection pain minimal, its application minimizes the time required for injection and reduces anxiety, thus ensuring patient comfort.

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