

UDK 616.33-089.86+338.27+663.1+614.275+616-092.4/6/9
DOI: 10.56871/CmN-W.2023.25.23.010

MEDICAL SOVEREIGNTY AND WAYS TO ACHIEVE IT ON THE EXAMPLE OF MINIMALLY INVASIVE GASTROSTOMY

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For citation: Gavshchuk MV. Medical sovereignty and ways to achieve it on the example of minimally invasive gastrostomy. Children's medicine of the North-West (St. Petersburg). 2023;11(4):83-87. DOI: <https://doi.org/10.56871/CmN-W.2023.25.23.010>

Received: 08.09.2023

Revised: 27.10.2023

Accepted: 11.12.2023

Abstract. *Introduction.* Medical sovereignty from imported consumables is an important component of State sovereignty. *The purpose of the article* is to propose ways to achieve medical sovereignty on the example of minimally invasive gastrostomy. *Materials and methods.* As part of the dissertation work, a theoretical study of the problem, a series of in vitro and in vivo experiments on laboratory animals, and a clinical study were conducted. *Results.* Original devices have been developed and experimentally tested, which together make up a specialized tube for percutaneous endoscopic gastrostomy. An original technology of minimally invasive gastrostomy is proposed – minimal gastrostomy through minilaparotomy, which reduces dependence on imported consumables. *Conclusions.* The presented original developments will not only make it possible to organize import substitution, but also exert informational pressure on foreign manufacturers to preserve imports.

Key words: *medical sovereignty; minimally invasive gastrostomy; import substitution; domestic developments.*

МЕДИЦИНСКИЙ СУВЕРЕНИТЕТ И ПУТИ ЕГО ДОСТИЖЕНИЯ НА ПРИМЕРЕ МАЛОИНВАЗИВНОЙ ГАСТРОСТОМИИ

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Для цитирования: Гавщук М.В. Медицинский суверенитет и пути его достижения на примере малоинвазивной гастростомии // Children's medicine of the North-West. 2023. Т. 11. № 4. С. 83–87. DOI: <https://doi.org/10.56871/CmN-W.2023.25.23.010>

Поступила: 08.09.2023

Одобрена: 27.10.2023

Принята к печати: 11.12.2023

Резюме. *Введение.* Медицинский суверенитет от импортных расходных материалов является важной составляющей государственного суверенитета. *Цель статьи* — предложить пути достижения медицинского суверенитета на примере малоинвазивной гастростомии. *Материалы и методы.* В рамках диссертационной работы проведено теоретическое изучение проблемы, серия экспериментов *in vitro* и *in vivo* на лабораторных животных, клиническое исследование. *Результаты.* Разработаны и апробованы в эксперименте оригинальные приспособления, составляющие в совокупности специализированную трубку для чрескожной эндоскопической гастростомии. Предложена оригинальная технология малоинвазивной гастростомии — минимальная гастростомия через мини-лапаротомию, снижающая зависимость от импортных расходных материалов. *Выводы.* Представленные оригинальные разработки не только позволят организовать импортозамещение, но и окажут информационное давление на иностранных производителей для сохранения импорта.

Ключевые слова: *медицинский суверенитет; малоинвазивная гастростомия; импортозамещение; отечественные разработки.*

INTRODUCTUON

State sovereignty requires the state to be able to autonomously meet its inhabitants' basic necessities. The health-care system plays a key role in this process. In addition to ensuring that the population is demographically balanced, its goal is to give all citizens access to healthcare. Including palliative care for terminally ill patients. Modern medical technology makes it possible to effectively provide medical care and minimize the impact on the patient. An example would be a gastrostomy puncture, in which the damage to the patient's tissues is confined to the area of the nascent nutritious fistula [1]. At the same time, traditional surgery via laparotomy [2–4] continues to be extensively used, which is more traumatic than gastrostomy itself. This phenomenon can be caused by the low availability of the necessary imported consumables, not just by the individual anatomical characteristics of patients. The price, which is initially expressed in foreign currency, increases when the final value is created and transferred from the foreign manufacturer to the domestic consumer. That is why, in the Russian Federation, puncture gastrostomy is used less often than in countries where the production of necessary consumables is localized. At the same time, the possibility of sanctions restricting imports remains. That has negatively affected the availability of modern puncture methods for gastrostomies. Therefore, in order to expand the number of minimally invasive gastrostomies available, a preventive set of steps is required.

THE PURPOSE OF THE ARTICLE

The article is aimed to propose ways to achieve medical sovereignty on the example of minimally invasive gastrostomy.

MATERIALS AND METHODS

The article describes the results of the thesis research work carried out at the Department of General Medical Practice of the Saint Petersburg State Pediatric Medical University (SPSPMU). The study was carried out with all the necessary conditions and was approved by the Ethics Committee of the University.

The formation of hypotheses was carried out by processing the data from the literature and the results of experiments with the help of well-known methods of cognition: analysis, synthesis, abstraction, generalization, induction, deduction, etc.

Prototypes of the inventions were made of biologically inert materials: stainless steel and silicone, authorized for use in the food industry.

To confirm the hypotheses and experimental testing of developments, we used simulation of the processes studied in simulation conditions *in vitro*. Conducted experiments on laboratory animals in the conditions of the experimental operating department of operative surgery and topographic anatomy named after Prof. F.I. Valker.

The clinical part of the work was carried out at the city hospital №26, where the SPSPMU base is located.

RESULTS

A special gastrostomy tube has been given as a key part of studying imported specialized sets for percutaneous puncture gastrostomy under the control of endoscopy by the pull method. The remaining elements of the kits can be replaced by standard reusable tools and consumables available in a conventional surgical facility. In the course of scientific research, the gastronomic tube is divided into three components, and their original analogues have been developed: a device for inserting a gastronomic tube through the front wall of the abdomen (patent RU 2669483 C1); a device for fixing the tube externally in the fistula of the stomach and small intestine for feeding and decompression, stopping the tube from moving into the hollow organ through the fistula (patent RU 2759574 C1); a device for forming the internal

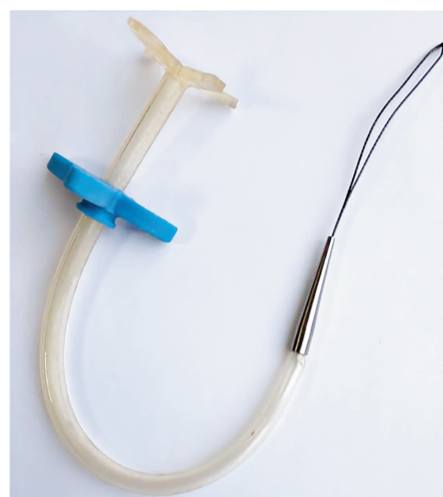


Fig. 1. Prototype of the original gastrostomy tube for percutaneous endoscopic gastrostomy, consisting of the developed products

Рис. 1. Прототип оригинальной гастростомической трубки для чрескожной эндоскопической гастростомы, состоящий из разработанных изделий

framework of the artificial fistula of the stomach and small intestine for nutrition and decompression (patent RU 2730978 C1) (Fig. 1).

The inventions' prototypes have been tested successfully on a simulator made for puncturing the stomach and the front wall of the abdomen during percutaneous endoscopic gastrostomy (patent RU 2765110 C1) [5] and on rabbits (Fig. 2, 3) [6].

Theoretical and experimental data obtained during the research allowed us to develop an alternative method of minimally invasive gastrostomy: minimal gastrostomy through mini-laparotomy (patent RU 2745655 C1) [7]. In the operation, a pressure method for forming a gastropex fistula is used, similar to a puncture gastrostomy. The main difference is the use of another type of access: mini-laparotomy, which allows you to reduce intraoperative injury and perform the intervention without additional visualization tools.

Minimal gastrostomy through mini-laparotomy is distinguished by a simple intervention technique. A mini-laparotomy is performed in a projection of an average of 1/3 of the stomach

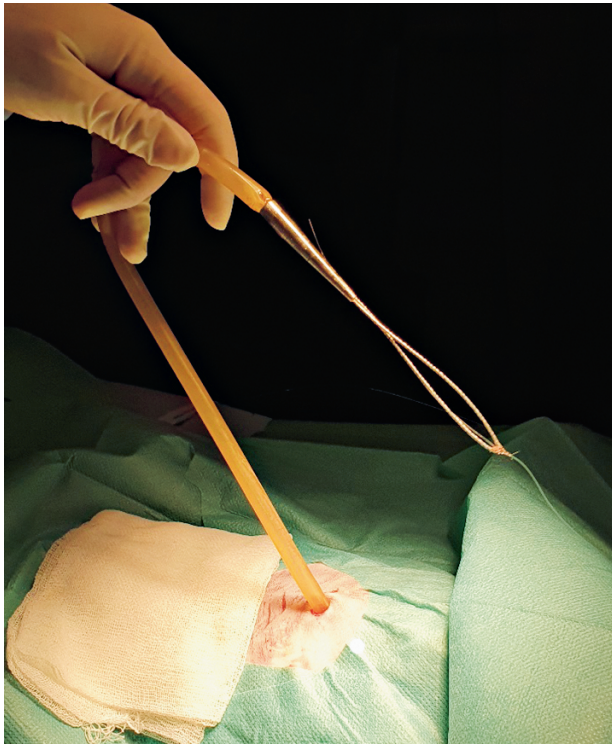


Fig. 2. Aprobation of a device for conducting a gastrostomy tube through the anterior abdominal wall in an experimental percutaneous endoscopic gastrostomy in a rabbit

Рис. 2. Апробация приспособления для проведения гастростомической трубки через переднюю брюшную стенку в экспериментальной чрескожной эндоскопической гастростоме у кролика

body with an additional orientation on the arrangement of the gastric gas bubble on the X-ray of the abdominal organs. In patients with a thin layer of subcutaneous fat, a 3 cm-long incision is sufficient. After opening the abdomen, the edges of the wound are removed by Farabef's hooks, and the front stomach wall is pulled up to the abdominal wall or even removed from the wound. At 1.5 cm from the edges of the future opening in the stomach wall, stitches are applied, of which two suture arms are oriented along the axis of the wound of the anterior abdominal wall (Fig. 4).



Fig. 3. Aprobation of the original external pressure plate during experimental percutaneous endoscopic gastrostomy in a rabbit

Рис. 3. Апробация оригинальной наружной прижимной пластинки при экспериментальной чрескожной эндоскопической гастростоме у кролика

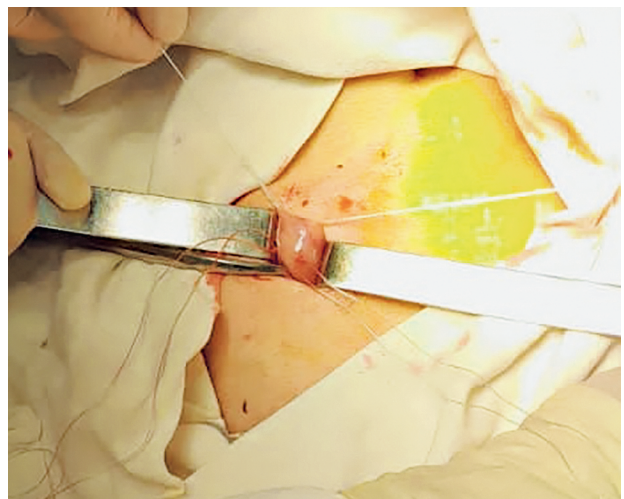


Fig. 4. Minimal gastrostomy through minilaparotomy: the stomach wall removed into the wound with 4 sutures-holders

Рис. 4. Минимальная гастростомия через мини-лапаротомию: выведенная в рану стенка желудка с 4 швами-держалками

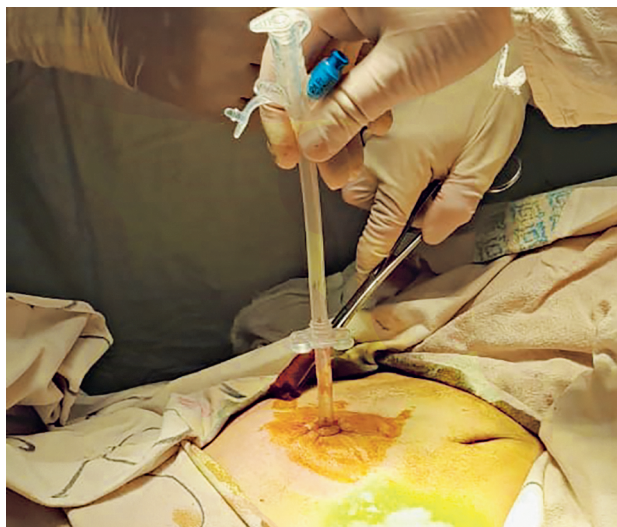


Fig. 5. Minimal gastrostomy via minilaparotomy: the final stage

Рис. 5. Минимальная гастростомия через мини-лапаротомию: завершающий этап

Between the suture holds, the stomach cavity is opened, and a gastrostomonic tube of the balloon type is started. The tube cylinder is filled in the opening of the stomach with water. The stomach wall is tightened behind the fixed tube to the abdominal wall, and the free ends of the suture are attached to the parietal peritoneum. The upper and lower joints along the wound are attached to the edges of the vaginal wall of the rectus. The surgical wound is then sutured, and the nutritional tube is fixed with an external pressure plate or by presentation to the skin (Fig. 5).

At the time of writing, the developed operation was successfully performed in 24 palliative patients with degree III–IV dysphagia, with no major complications requiring surgery.

DISCUSSION

The medical benefits of puncture gastrostomy due to its low invasiveness and the interest of disposable consumables manufacturers in expanding the market led to the rapid recognition and dissemination of the technique. At the same time, the economic efficiency of puncture gastrostomy decreases with distance from countries where the production of consumables is located. Compulsory import restrictions as a result of the sanctions policy formally reduce the market but preserve the income of foreign producers through parallel import technologies, so the economic damage is to the country against which the restrictions are imposed. At the same time, foreign producers are

not interested in the emergence of competitive products on the market, so information on the readiness to organize Russian production stimulates the preservation of imports. At the time of writing, direct deliveries of specialized medical products for gastronomy from unfriendly countries remain.

In view of economic laws, the launch of domestic production against the background of the continued import of necessary medical products is not profitable in the short term. The use of alternative minimally invasive technology for the formation of nutritious fistulas is more advantageous both from an economic point of view and from the point of view of a value-oriented concept of health care.

Creating domestic versions of needed products and new ways to do the intervention can help lower reliance on imports. These ideas can be applied to other surgical technologies as well.

CONCLUSIONS

The developed original consumables for minimally invasive gastrostomy will not only allow for domestic production but will also put information pressure on foreign manufacturers to keep imports.

Minimal gastrostomy through mini-laparotomy does not require expensive imported consumables and can be considered a choice operation when puncture techniques are not available.

ADDITIONAL INFORMATION

The author read and approved the final version before publication.

Funding source. This study was not supported by any external sources of funding.

Consent for publication. Written consent was obtained from the patient for publication of relevant medical information within the manuscript.

Experiments with animals were carried out in accordance with international rules (Directive 2010/63/EU of the European Parliament and of the Council of the European Union of September 22, 2010 on the protection of animals used for scientific purposes).

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

Автор прочитал и одобрил финальную версию перед публикацией.

Источник финансирования. Автор заявляет об отсутствии внешнего финансирования при проведении исследования.

Информированное согласие на публикацию.

Автор получил письменное согласие пациентов на публикацию медицинских данных.

Эксперименты с животными проводили в соответствии с международными правилами (Директивой 2010/63/EU Европейского парламента и Совета Европейского союза от 22 сентября 2010 года по охране животных, используемых в научных целях).

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