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The penile prosthesis implantation: the current experience of surgical treatment for erectile dysfunction.

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Abstract

Objective. The purpose of this work was to describe the Russian experience in applying European clinical recommendations, as well as a statistical description of a group of patients with erectile dysfunction who received surgical treatment.

Methods. A retrospective study was conducted on a group of patients with primary implantation and re-implantation of a penile prosthesis. The inclusion criteria for the study were: a completed patient medical record; including anthropometric parameters of the patient; diabetic status; characteristics of penile prostheses; type of surgical intervention and the availability of a full set of laboratory tests.

Results. With strict adherence to European clinical guidelines, no cases of breakage or development of prosthetic infection were identified in patients after primary implantation of a penile prosthesis (314 people). About half of the patients (144 people) with ED who underwent primary penile replacement had a BMI <27.14. Three-piece penile prostheses were most commonly implanted in patients ≤52 years of age. A prognostic model for assessing the risk of developing diabetes has been proposed, taking into account the parameters of BMI, blood glucose and HbAc1.

Conclusions. The strict sequence of actions of the operating team and their compliance with European clinical recommendations allows us to minimize the occurrence of prosthetic infections during the primary implantation of a penile prosthesis. Predisposition to diabetes, which can be assessed using a prognostic model, is recommended to be taken into account when developing a strategy for surgical treatment of patients with erectile dysfunction.

Keywords: *erectile disfunction; diabetes mellitus; implantation; penile prosthesis; prosthesis infection.*

Introduction

One of the current healthcare challenges is the problem in the field of diagnosis and treatment of erectile dysfunction (ED). The rapid increase in the incidence of ED is explained by many factors, including deteriorating environmental conditions, obesity, insulin resistance and diabetes mellitus, cardiovascular, and autoimmune diseases [1]. In this context, implantation of a penile prosthesis is one of the effective methods of radical treatment of ED [2]. Implantation can significantly improve not only the physical, but also the psychological condition of patients [3]. According to European clinical guidelines [4], penile replacement is considered the last line of therapy in the treatment of ED, when conservative treatment no longer brings satisfactory results. Along with the increase in the number of implantations, the number of postoperative complications, such as the breakdown of prosthetic components and infection, also increases proportionally [5]. To reduce adverse outcomes, Chung et al. 2022 [6] proposed a consensus of methods and principles of surgical treatment based on generalized international experience in implantation of three-component penile prostheses. The purpose of this work was to describe

the Russian experience in applying European clinical recommendations within the framework of consensus [6], as well as a statistical description of a group of patients with erectile dysfunction.

Materials and Methods

The study is based on an analysis of comprehensive medical data from 348 patients aged 20 to 75 years who underwent surgical treatment: implantation/reimplantation, or explantation of a penile prosthesis from 2021 to 2023. All patients provided written informed consent. Publication ethics statements patients cohort were approved by the institutional review board of the Russian Medical Academy for Continuing Professional Education (RMANPO) №15.2022.10.11. The inclusion criteria for the study were: a completed patient medical record including anthropometric parameters (weight, height) of the patient; diabetic status; characteristics of penile prostheses (type and brand); type of surgical intervention (implantation, reimplantation, explantation) and the availability of a full set of laboratory tests; as well as the availability of informed consent for the processing of medical data.

The surgical intervention was performed by a permanent surgical team. Surgical treatment was performed in accordance with the method of K.A. Menshchikov, developed for implantation of three-component penile prostheses (certificate of state registration No. RU 2023621184). The essence of this method is to follow a strict sequence of actions when performing penile implantation. The sequence of actions of each member of the surgical team was worked out in advance for each type of surgical procedure. Preparation for surgery, surgery and subsequent rehabilitation were in strict accordance with European clinical guidelines [4].

Statistical analysis was performed using StatTech software. 3.1.8 (developer - Stattekh LLC, Russia).

Quantitative indicators were assessed for compliance with normal distribution using the Shapiro-Wilk test (with the number of subjects less than 50) or the Kolmogorov-Smirnov test (with more than 50 participants).

In the absence of a normal distribution, quantitative data were described using the median (Me) and lower and upper quartiles (Q1–Q3).

Categorical data were described using absolute values and percentages.

Comparison of two groups for quantitative indicators whose distribution differed from normal was performed using the Mann-Whitney U test.

Comparison of three or more groups on a quantitative indicator, the distribution of which differed from normal, was performed using the Kruskal-Wallis test, post hoc comparisons - using Dunn's test with Holm's correction.

Comparison of percentages in the analysis of multifield contingency tables was performed using the Pearson chi-square test.

The direction and strength of the correlation between two quantitative indicators were assessed using Spearman's rank correlation coefficient (if the distribution of indicators was different from normal).

A prognostic model characterizing the dependence of a quantitative variable on factors was developed using the linear regression method.

The construction of a prognostic model of the probability of a certain outcome was carried out using the logistic regression method. Nigelkirk's R^2 was used as a measure of the portion of variance that can be explained by logistic regression.

To assess the diagnostic significance of quantitative characteristics in predicting a specific outcome, the ROC curve analysis method was used. The separating value of a quantitative characteristic at the cut-off point was determined by the highest value of the Youden index.

Results

Below are the results of a comparison of indicators for which statistically significant differences were found. In the remaining cases, no statistical differences were found, and therefore it can be considered that in these cases the comparison groups were homogeneous.

Table 1 provides an indication of age differences in the use of each type of penile prosthesis.

Relationship between BMI and the type of surgery is described in Table 2. Table 3 presents surgical outcomes according to type of surgery. Summarized Table 4 gives an idea of the characteristics of the two groups - with diabetes and without diabetes.

Taking into account the importance of the relationship between Diabetes and erectile dysfunction, a predictive model was developed to determine the probability of the “Diabetes” indicator depending on the “HbAc1” indicator, the “Blood Glucose” indicator, and the “BMI” indicator using the binary logistic regression method. The number of observations was 292. The observed dependence is described by the equation:

$$P = 1 / (1 + e\text{-}z) \times 100\%$$

$$z = -17.153 + 1.510X_{HbAc1} + 0.666X_{Blood\ glucose} + 0.107X_{BMI}$$

where P is the probability of Diabetes, X_{HbAc1} – HbAc1 (%), $X_{Blood\ glucose}$ – Blood glucose (mmol/l), X_{BMI} – BMI (kg/m^2)

The resulting regression model is statistically significant ($p < 0.001$). Based on the Nigelkirk coefficient of determination, the model explains 64.2% of the observed variance of the "Diabetes" indicator.

With an increase in HbAc1 by 1%, the chances of Diabetes increased by 4.526 times. With an increase in blood glucose by 1 mmol/l, the chances of diabetes increased by 1.946 times. With an increase in the "BMI" indicator by 1 kg/m^2, the chances of Diabetes increased by 1.113 times.

Table 1: Relationship between "Full years" and "Prosthesis type".

Prosthesis type	Categories	Full years (full years)			p
		Me	$Q_1 – Q_3$	n	
Three-component prosthesis	Coloplast Titan Touch	49	39 – 57	251	0,002*
	AMS 700LGX IZ	50	40 – 62	23	
	AMS 700 CX	52	35 – 64	7	
One-component prosthesis	Coloplast Genesis	59	47 – 70	31	
	Boston Scientific Tactra	60	54 – 65	10	

* – differences are statistically significant ($p < 0.05$) (*method used: Kruskal–Wallis test*).

Table 2: Relationship between "BMI" and the "Surgery type"

Measure	Category	BMI (kg/m^2)			p
		Me	$Q_1 – Q_3$	n	
Type of operation	Primary implantation	27,12	24,80 – 29,71	288	0,042*
	Reimplantation	29,41	25,78 – 31,76	27	
	Explantation	27,95	26,26 – 32,13	6	

* – differences are statistically significant ($p < 0.05$) (*method used: Kruskal–Wallis test*).

Table 3: Relationship between "Outcome" and the "Surgery type"

Indicator	Category	Outcome			p
		No infection breakage	Prosthetic infection	Breakage	
Type of surgery	Primary implantation	314 (95,7)	0 (0,0)	0 (0,0)	< 0,001*
	Reimplantation	13 (4,0)	8 (66,7)	6 (85,7)	
	Explantation	1 (0,3)	4 (33,3)	1 (14,3)	

* – differences are statistically significant ($p < 0.05$) (*method used: Pearson Chi-square*).

Table 4: Relationship between "Age", "Weight", "BMI", "Blood glucose", "HbAc1" and "Diabetic status"

Measure	Category	Descriptive statistics			p
		Me	$Q_1 – Q_3$	n	
Age (full years)	No diabetes	49	37 – 58	265	< 0,001*
	Have diabetes	56	48 – 65	61	
Weight (kg)	No diabetes	85	79 – 95	260	0,008*
	Have diabetes	92	82 – 103	61	
BMI (kg/m^2)	No diabetes	27,08	24,79 – 29,56	259	0,003*
	Have diabetes	28,71	25,51 – 33,26	61	
Blood glucose (mmol/l)	No diabetes	5,17	4,88 – 5,66	240	< 0,001*
	Have diabetes	7,43	6,10 – 9,04	57	
HbAc1 (%)	No diabetes	5,04	4,84 – 5,34	243	< 0,001*
	Have diabetes	6,94	5,73 – 7,96	58	

* – differences are statistically significant ($p < 0.05$) (*method used: Mann–Whitney U test*)

Table 5: Relationship between model predictors and the probability of identifying "Diabetes"

Predictors	Unadjusted		Adjusted	
	COR; 95% CI	p	AOR; 95% CI	p
HbAc1	10,642; 5,534 – 20,471	< 0,001*	4,526; 1,984 – 10,329	< 0,001*
Blood glucose	4,378; 2,892 – 6,626	< 0,001*	1,946; 1,123 – 3,370	0,018*
BMI	1,129; 1,055 – 1,207	< 0,001*	1,113; 1,005 – 1,234	0,040*

Discussion

The leaders in the global penile prosthesis market are Coloplast and Boston AMS [7] and they both produce one-piece and three-piece penile prostheses. The selection and use of certain types of penile prostheses [8] is carried out depending on the individual preferences and physiological characteristics of each patient. In addition, we recommended one type of prosthesis to patients depending on the patient's physiological condition and taking into account the surgical risks. According to our data, three-component prostheses are more often implanted in patients under 52 years of age (see Table 1). This type of prosthesis is characterized by the greatest physiology and functionality, which maximizes the realism of sexual intercourse. This aspect provides a complete solution to the psychological problems and fully rehabilitates the patient's sexual life. Also, a three-component penile prosthesis allows retention of the length and width of the penis, maximally stretching the walls of the capsule when filling. Older patients more often choose one-component penile prostheses due to their affordability, lower operational risks (due to a smaller wound surface), and speedy rehabilitation after surgery.

Table 2 shows us the characteristics of the group of patients receiving surgical treatment for ED for the first time. Of the 288 patients with primary penile implantation, half of them (144 people) had a normal BMI <27.14. This suggests that ED in a significant proportion of patients (at least 144 patients) is not associated with metabolic syndrome and its associated diseases. The causes of ED in these patients appear to lie on a different plane. It is also significant that for cases in the reimplantation group, the median BMI Me (BMI) = 29.41. This means that half of the 27 reimplantation patients suffered from metabolic syndrome, which appears to have caused both the cases of prosthetic failure and the cases of prosthetic infection after implantation.

Table 3 shows an important result - for primary implantation there were no cases of failure and prosthetic infection. We can explain this by strict adherence to European clinical guidelines [4], as well as by the implementation of our method, which consists of observing a strict sequence of actions of each member of the surgical team. The sequence of actions of each member of the surgical team is well known and practiced until it becomes automatic. The presence of cases of reimplantation and explanation in our database is due to the fact that patients, after unsuccessful primary implantation performed by other surgical teams, turned to our surgical team for help. However, the risk of recurrent prosthetic infection remains high, including in the practice of our surgical team. We suggest that additional research into cases of secondary prosthetic infections is needed in order to develop recommendations for their prevention. On the other hand, we discovered an important pattern: reimplantation associated with failures were often caused by tube failure. This is due to the excess standard length of the tubes from the implant cylinders to the pump in conditions of small scrotal volumes in patients with short stature, which often leads to malfunction of the prosthesis.

A significant part of statistical analysis is related to the comparison of two groups of patients - with diabetes and without diabetes. Table 4 provides a comprehensive description of the groups of patients with and without diabetes based on many characteristics. The ratios of signs in the two groups of patients with ED are comparable to those in the population. We cannot note any features in patients with ED depending on their diabetic status. However, we must note that the dynamics of the increase in the incidence of diabetes mellitus throughout the World should be taken into account [9]. In our opinion, it is necessary to pay attention to the relationship between the presence of this endocrine disease in a patient with ED and the outcomes of his surgical treatment and his long-term prospects. To this end, based on our database, we proposed a prognostic model that allows us to determine the risk of diabetes (susceptibility to diabetes) in a group of patients suffering from ED. This predictive model includes parameters such as HbAc1 level, blood glucose level and BMI. This model can help assess the susceptibility of a patient with ED to diabetes and, in

accordance with the risk of developing diabetes, adjust preparation for surgical treatment of ED and subsequent rehabilitation.

As part of this approach, we recommend monitoring patients' HbAc1 levels. There is a known relationship between the level of glycated hemoglobin (HbAc1) and the development of acute prosthetic infection [10,11]. Statistically significant differences in HbAc1 levels between patients with and without diabetes highlight the importance of controlling this indicator to prevent serious postoperative complications.

A limitation of this work is that factors such as smoking, alcohol or drug use were not collected and were not included in the study.

Conclusions

In this article, we presented a statistical analysis of a group of patients with ED. An important result of our analysis was the fact that about half of the patients had a normal BMI at the time of primary implantation. We attribute this to the fact that ED may well develop in the absence of risk factors such as obesity and diabetes.

According to the data obtained, three-component prostheses were implanted in the vast majority of patients due to significant advantages over single-component prostheses, which were periodically chosen by older patients due to their lower cost and ease of use.

Noteworthy is the relationship between the concentration of glucose in the blood, BMI and the level of glycated hemoglobin, which turned out to be informative and statistically significant in the context of determining the likelihood of developing prediabetes and subsequently diabetes.

The strict sequence of actions of the operating team and their compliance with European clinical recommendations allows us to minimize the occurrence of prosthetic infections during the primary implantation of a penile prosthesis.

Predisposition to diabetes, which can be assessed using a prognostic model, is should be accounted for when developing a strategy for surgical treatment of patients with ED.

Declarations

Disclosure statement

The authors reported no potential conflict of interests.

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