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Interventional treatment for type 2 diabetes

Interwencyjne leczenie cukrzycy typu 2

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S u m m a r y

Obesity and type 2 diabetes are currently the most serious health problems in developed and developing countries. According to standards of treatment of diabetes, especially with obesity, weight reduction is an essential element of therapy. However, to obtain a decrease in weight and its maintenance is often very difficult. This is due to the limited effectiveness of the available methods and to the reluctance of patients to maintain the rigors of dietary and physical activity. On the other hand, it is quite well known already that bariatric surgery is an effective way to achieve a significant reduction in body weight. Now several million such surgical interventions has already been carried out all over the world. Since the introduction of the laparoscopic technique, they are getting more safe, effective, and the variety of types of operation allows to adjust the appropriate method individually for each patient.

Review briefly presents the different types of operations, the rules for eligibility and preparing patients for surgery, as well as the most important problems which the physician should remember in care about the patient after surgery. These are also an alternative to surgery, less invasive methods of intervention treatment of diabetes and obesity described.

S t r e s z c z e n i e

Otyłość i cukrzyca typu 2 należą obecnie do najpoważniejszych problemów zdrowotnych w krajach rozwiniętych i rozwijających się. Według standardów leczenia cukrzycy, zwłaszcza z towarzyszącą otyłością, redukcja masy ciała stanowi zasadniczy element terapii. Jednak uzyskanie spadku wagi i jego utrzymanie jest często bardzo trudne. Wynika to z ograniczonej efektywności stosowanych metod oraz z niechęci pacjentów do utrzymywania rygorów dietetycznych i aktywności fizycznej. Z drugiej strony, od dawna już wiadomo, że skutecznym sposobem osiągnięcia istotnej redukcji masy ciała jest operacja bariatryczna. Obecnie na świecie przeprowadzono już kilka milionów takich zabiegów. Od czasu wprowadzenia techniki laparoskopowej są one coraz bardziej bezpieczne, skuteczne, a wielość typów operacji pozwala na dostosowanie odpowiedniej metody indywidualnie do każdego pacjenta.

Praca krótko przedstawia różne rodzaje operacji, zasady kwalifikowania i przygotowywania pacjentów do zabiegu, a także najważniejsze problemy, o których lekarz internista powinien pamiętać, prowadząc pacjenta po operacji. Wspomniane są także alternatywne do operacji, mniej inwazyjne metody interwencyjnego leczenia cukrzycy i otyłości.

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Obesity is the most common metabolic disease nowadays. According to the World Health Organization (WHO) it is now reaching an epidemic size, and is the biggest health problem in developed and developing countries. WHO estimates that in 2008 there were 200 million of obese men and 300 million obese women all over the world, and 2-3 times as many were overweight. At the end of 2009 more than 45% men in Poland were overweight and 17% of them were obese (1). Among women the figures reached 30 and 15% respectively (2). Obesity, especially abdominal one, is known to contribute to the development of many metabolic disorders and diseases, including type 2 diabetes. About half of diabetics are thought to be obese (3). Nearly 350 million people are suffering from diabetes currently. In Poland, as is evidenced by NATPOL (III) research, 6-8% of the adult population are affected (4).

Standard procedures, regularly updated by the diabetics associations, invariably involve primarily the modification of lifestyle, and secondly a pharmacological treatment using one (metformin) or more drugs, including insulin (5, 6). Although weight reduction is an essential element of the therapy, experience shows that it is often difficult to obtain. This results on the one hand from a limited

effectiveness of the methods and on the other one from the patients reluctance to maintain the rigorous diet and physical activity, especially long-term ones. This is why less than half the patients obtain the therapeutic aims (7).

An effective method of significant weight reduction, known for dozens of year, is bariatric surgery. The first attempts of jejunum-to-ileum or colon anastomosis and DeWind and Payne's intestinal exemption treatment were made in 1950-60. In 1971 the first gastroplasty was performed, while the years 1970-80 brought on a vertical division of the upper part of the stomach and securing the channel along the lesser curvature with grid (vertical banded gastroplasty – VBG) or drain (silastic ring vertical gastroplasty – SRVG). The 1980s were marked of adjustable clamps. In the next years the operating techniques were developed and modified until the ones known now. A real breakthrough was the introduction of laparoscopic technique in the 1990s; it is now widely used in bariatric surgery (8-10).

For about 20 years the beneficial metabolic effects of body mass surgery have been highlighted (11). Currently there is abundant evidence that this treatment causes a rapid, substantial and long-lasting improvement in glycemic control in patients with type 2 diabetes (12-14). For this reason the term of metabolic surgery has come into use, although the concept was already considered at the end of 1970s. Metabolic surgery is defined as a surgical technique that modifies the digestive tract so that the change in the passage of food results in improving glycemic control in diabetes as a result of launching some mechanisms independent of weight reduction. Thus, the first purpose of metabolic surgery is not a weight reduction, but metabolic improvement.

A high effectiveness combined with lower perioperative complications risk resulted in a rapid growth in the number of operations performed worldwide. In 2013 179,000 such procedures were performed in the US (15). In the years 1993-2006 in Poland 2,584 such operations were made (16), and currently about 1,500 are performed annually. Current indications for the procedure, as defined in the recommendations by the Polish Association for the Study of Obesity, include severe obesity (BMI $\geq$ 40 kg/m^2) or II° obesity (BMI = 35 to 39.9 kg/m^2) with associated diseases, whose course can improve following a surgery, such as type 2 diabetes and other metabolic disorders, cardiovascular diseases, respiratory, bone and joint problems as well as severe psychological problems among people aged 18 to 60 (17). Similar criteria have been determined by other scientific societies, e.g. European Society for Endoscopic Surgery (EAES), the American Gastroenterological Association (AGA) or the American Society of Cardiology (AHA). Recently International Diabetes Federation (IDF) recommends considering an operation also for people with BMI 30-35 kg^2 with poorly controlled type 2 diabetes despite optimal pharmacological treatment, especially with an increased cardiovascular risk. Contraindications for the surgery include lack of earlier attempts at conservative treatment, inability to observe recovery, not stabilized mental illness and emotional disorders, alcoholism, drug addiction, lack of support from family or caregivers.

The bariatric operations currently performed can be divided into restrictive, i.e. those which limit the amount of food consumed, or reducing absorption (exempting, malabsorption) or restrictive-excluding, so those which combine the two previous techniques. The first are technically easier to perform, shorter and less aggravating for the patient. Exempting treatment results in a greater loss of body weight and is more effective, though it increases the risk of malnutrition. There are many surgical methods, which, as has been mentioned before, are constantly refined and developed, but in practice the most common ones include:

- laparoscopic adjustable gastric binding (LAGB),
- sleeve gastrectomy (SG),
- Roux-an-Y Gastric Bypass (RYGB).

A modification of the last one, which disconnects a larger section of the digestive tract, is the co-called Scopinaro procedure, i.e. BPD: biliopancreatic diversion or its variant, BPD-DS: biliopancreatic diversion-duodenal switch.

Adjustable gastric band is a very common procedure (46% of all bariatric surgeries in 2010) (18), due to positive results with a favorable safety profile, as demonstrated in many studies. Perioperative mortality for this method is < 0.1% within 30 days (19). The treatment is fully reversible and causes low nutritional deficits. For these reasons in 2011 American food and Drug Agency (FDA) allowed its application for patients with BMI of 30-35 kg/m^2, who also suffer from obesity-dependent diseases. Disadvantages of this method include the need of strict dietary control, possible vomiting, a possibility that the clamp can move or grow into the wall of the stomach. Less than 25% of the patients maintain good results after 14 years of observation, and 68% require repetition of surgery.

The most frequently performed operation in the world today is sleeve gastrectomy. In 2013, this surgery accounted for 42% of all bariatric surgeries in the United States (15). It involves removing a vast majority of the stomach and leaving only a small part along the lesser curvature. The advantages of such operations include a significant reduction in the capacity of the stomach and the removal of the ghrelin-producing part with a subsequent significant decline in its concentration and a growing concentration of YY (PYY) peptide. The disadvantage is a long anastomosis line and a possibility of a leak.

Another frequently performed procedure, although much more invasive, is Roux-en-Y gastric bypass. While the two previous techniques might be considered restrictive, RYGB is a mixed type, and as such it limits absorption. In 2013 it accounted for 34% of all bariatric surgeries carried out in the United States (15). The procedure consists in transecting with staplers a part of cardia area of approx. 20 ml capacity, which is then connected by anostomosis with a selected loop of the small intestine. This excludes the remaining part of the stomach, duodenum and the initial 60-100-cm section of the jejunum. The proxi-

mal end of the small intestine, formed after the resection, is connected end-to-side with a further intestinal loop, just about 100 cm from the stomach body and it is only at this point that the food mixes with pancreas enzymes and bile, which enables efficient digestion and absorption. The advantages of this method are: a significant reduction in the amount of food received and reversibility. The disadvantages include possible band breaking, blockade between the intestines and stomach, the need to comply with a diet and vitamin supplementation for the rest of patient's life. RYGB can be considered the "gold standard" of the bariatric surgeries. For over 40% patients operated in this way remission of diabetes was reported and 69% do not use medication even after 3 years of the procedure (for the sleeve gastrectomy the figure was 43%). Complications associated with Roux-en-Y are about 4-5%, the mortality rate is 0.2%, and embolism (pulmonary and venous) 0.4%. Only 3-5% of the patients require reoperation.

Generally it is believed that, regardless of type, such operations should be performed by experienced surgeons in the centers evaluated by independent monitoring organizations. Clinical studies indicate that bariatric treatment in patients with type 2 diabetes lead to a significant reduction in body weight, and considerably improve glycemic control and metabolic rates.

Tables 1 and 2 show the results of a meta-analysis of Gloy et al. (20), covering 796 patients with BMI of 30-50 kg/m^2 and diabetes, which compared the impact of conservative and surgical treatment (LAGB, RYGB, BPD) on body weight and metabolic indicators in obese patients with type 2 diabetes, based on the results of 11 clinical observations.

The results of surgeries on patients with type 2 diabetes with smaller obesity (BMI < 35 kg/m^2) based on 18 selected publications are presented in table 3 (21).

The data shows that remission of diabetes and the possibility of discontinuation of hypoglycemic treatment was obtained for 86.6% of the patients. Furthermore, 30.1% of the patients treated with insulin prior to surgery achieved a correct metabolic control. A clear and often sharp decline in sugar level is usually seen already in the first few days after surgery, even before a significant weight reduction. The mechanisms of this phenomenon are not well understood. The impact of changes in food absorption and passage on insulin sensitivity and beta cell function have been taken into consideration; studies have indicated a significant post-surgery increase in rapid insulin response onto intravenous as well as for oral administration of glucose (22, 23). It is believed that this may result from a rapid decline of the insulin resistance and increase in the secretion of glucagon-like peptide 1 (GLP-1).

Two theories: of the lower and upper gastrointestinal tract are under discussion. The first one claims that food swiftly moves to the distal part of the intestine in order to increase the production of GLP, while the other hypothesis assumes a lack of activation of unspecified diabetogenic factors in the upper part of the gastrointestinal tract resulting from the bypass produced in the surgery (24). Potential mechanisms also include changes in the metabolism of bile acids, affecting for example liver gluconeogenesis and changing the bacterial flora of the gastrointestinal tract. Among the therapeutic purposes as defined by the diabetologic societies is not only good glycemic control, but also improvement in the lipid profile and normalization of blood pressure. Only a low percentage of patients with type 2 diabetes treated conservatively manage to achieve and then maintain these aims (25). In contrast, the bariatric surgery helps to obtain a favorable blood lipid profile for 70% patients and a blood pressure drop in 78.5% of them, which in turn contributes to a substantial decrease

Table 1. Diabetes remission after bariatric surgeries vs conservative treatment in obese patients with type 2 diabetes. Patients treated with LAGB were compared with those treated with other techniques in a sub-analysis.

Study or subgroup	Bariatric surgery		Control		Risk ratio (95% CI)	Weight (%)	Risk ratio (95% CI)
	No of events	Total	No of events	Total			
Adjustable gastric banding							
Dixon 2008 (2 years)	22	29	4	26		35.2	4.9 (2.0 to 12.4)
Subtotal	22	29	4	26		35.2	4.9 (2.0 to 12.4)
Test for heterogeneity: Not applicable							
Test for overall effect: z – 3.38, P < 0.001							
Other bariatric surgery techniques							
Laing 2013 (1 year)	28	31	0	70		21.6	126.5 (8.0 to 2007.6)
Mingrone 2012 (2 years)	34	38	0	18		21.7	33.6 (2.2 to 519.3)
Schauer 2012 (1 year)	34	99	0	41		21.5	29.0 (1.8 to 461.8)
Subtotal	96	168	0	129		64.8	49.8 (10.1 to 243.9)
Test for heterogeneity: τ^2 – 0.00, χ^2 – 0.66, df – 2, P – 0.72, I^2 – 0%							
Test for overall effect: z – 4.81, P < 0.001							
Total (95% CI)	118	197	4	155	0.005 0.1 1 10 200	100.0	22.1 (3.2 to 154.3)
Test for heterogeneity: τ^2 – 2.58, χ^2 – 9.50, df – 3, P – 0.02, I^2 – 68%							
Test for overall effect: z – 3.12, P – 0.002					Favours control / Favours bariatric surgery		
Test for subgroup differences: χ^2 – 6.05, df – 1, P – 0.01, I^2 – 83.5%							

Table 2. Metabolic syndrome remission after bariatric surgeries vs conservative treatment in obese patients with type 2 diabetes. Patients treated with LAGB were compared with those treated with other techniques in a sub-analysis.

Study or subgroup	Bariatric surgery		Control		Risk ratio (95% CI)	Weight (%)	Risk ratio (95% CI)
	No of events	Total	No of events	Total			
Adjustable gastric banding							
Dixon 2008 (2 years)	21	29	4	29		13.8	5.3 (2.1 to 13.4)
Dixon 2008 (2 years)	9	19	2	24		7.4	5.7 (1.4 to 23.3)
O'Brien 2006 (2 years)	14	15	7	15		24.7	2.0 (1.1 to 3.5)
O'Brien 2006 (2 years)	9	9	6	10		26.5	1.6 (1.0 to 2.7)
Subtotal	53	72	19	78		72.4	2.7 (1.4 to 5.2)
Test for heterogeneity: τ^2 - 0.29, χ^2 – 9.23, df – 3, P – 0.03, I^2 – 68%							
Test for overall effect: z – 2.91, P – 0.004							
Other bariatric surgery techniques							
Schauer 2012 (1 year)	57	92	13	46		27.6	2.2 (1.3 to 3.6)
Subtotal	57	92	13	46		27.6	2.2 (1.3 to 3.6)
Test for heterogeneity: Not applicable							
Test for overall effect: z – 3.16, P – 0.002							
Total (95% CI)	110	164	32	124	0.005 0.1 1 10 200	100.0	2.4 (1.6 to 3.6)
Test for heterogeneity: τ^2 – 0.11, χ^2 – 7.82, df – 4, P – 0.10, I^2 – 49%							
Test for overall effect: z – 4.06, P < 0.001					Favours control / Favours bariatric surgery		
Test for subgroup differences: χ^2 – 0.23, df – 1, P – 0.63, I^2 – 0%							

Table 3. The results of bariatric surgeries: change in body mass index (BMI), fasting glucose and glycated hemoglobin (HbA1c), as well as the percentage of patients that discontinued hypoglycemic medicine, remission percentage and perioperative mortality.

Author, year	Change following surgery			% of patients without diabetic medicine after surgery	Remission (%)	Complications (%)	Mortality (%)
	BMI (mean, kg/m^2)	Glucose fasting (mean, mg/dl)	HbA1c (mean, %)				
Lee, 2011	7.1	53.5	3.8	90	55	11.3	0
Boza, 2011	9.8	35.1	1.6	–	83.3	33.3	0
De Sa, 2011	7.9	82.2	2.4	74.1	48.1	25.9	0
Huang, 2011	7.1	100.7	3.3	90.9	63.3	9.1	0
Scopinaro, 2011	5.3	71	2.8	83.3	30	16.7	0
Shah, 2010	5.9	143.8	4.0	100	100	0	0
Lee, 2010	6.4	107.2	3.0	–	50	0	0
DePaula, 2009	–	109.9	–	91.2	63.7	10.3	0
DePula, 2009	3.9	116.1	2.8	95.7	65.2	7.3	0
Ramos, 2009	2.7	75	2.0	90	–	0	0
Ferzli, 2009	0.2	54	0.9	14	14	0	0
Geloneze, 2009	0.5	27	1.1	0	0	16.7	0
Chiellini, 2009	5.4	–	2.8	100	–	–	0
Lee, 2008	8.5	–	1.7	–	89.5	4.5	0
Scopinaro, 2007	6.3	131.7	–	100	–	–	0
Cohen, 2006	1.3	–	–	100	100	0	0
Chen, 2006	–	58	–	100	100	0	0
Noya, 1998	5.6	–	–	90	90	20	0

in the risk of cardiovascular heart disease (26). The operation also reduces the risk of developing cancer and improves physical performance. Bariatric treatment in general can be considered to be life-saving, as many-year prospective observational study has shown that it reduces the risk of death for any reason among obese people treated surgically when compared to using conservative methods (27).

In terms of qualifying the patients for surgery as well as pre- and post-surgery the optimal procedure must include a conversation with the patient on various methods of treating obesity, the availability of drugs to reduce body weight and the possibility of bariatric surgery; then patent should be transferred to the operating team composed of a bariatric surgeon, a specialist in obesitology, a nutritionist, and in case of post-surgery problems a gastrologist experienced in proceeding after such treatments. In practice, all the above-mentioned specialists must be usually replaced by an endocrinologist (diabetologist) or family doctor, who has no opportunity to cooperate with other professionals. Before the surgery health problems (diabetes, hypertension, sleep apnea) must be dealt with, and effective contraception method for women at a reproductive age must be recommended, but without estrogen, due to the increase in the risk of pulmonary embolism. The patient should stop smoking before and after surgery due to the adverse effects of tobacco on the healing of wounds and the activity of the respiratory system. In people with high gastro-esophagal reflux it is recommended to perform an endoscopic examination, while in patients with the history of embolism should have a filter inserted in the inferior vena cava. It is recommended to assess the concentration of vitamin D and iron and supplement for the shortages, if necessary. A week before the surgery and after surgery do not use NSAIDs for fear of the development of ulcer in the anastomosis. Patients with diabetes must discontinue metformin for a dozen days prior to surgery (the possibility of hypoglycemia after surgery) as well as after the procedure, in case of risk of metabolic acidosis. After the surgery insulin must be used so that glucose is 140-180 mg/dl and, in cases of persistent hyperglycemia oral medicine should be reapplied.

Despite the fact that blood pressure usually remains unchanged after the surgery, it is recommended to discontinue diuretics and possibly replace them with calcium channel blockers. They should be administered with greater caution as it can induce orthostatic hypotonia. Over the next months the overall health condition should be evaluated for recovery from the symptoms of diseases, for example: gastroesophageal reflux or incontinence, which enables to discontinue relevant drugs; reducing the amount of fat face, i.e. CPAP mask mismatch; improvement of the lipid profile-medicine reduction/discontinuation. Also the possibility of a deterioration in the absorption of drugs, especially after RYGB surgery, must be taken into account. This is especially important when applying contraceptives or thyroid hormones etc. For this reason, medications must be in their basic forms, fast acting, and slowly released forms should be avoided. Shortages of vitamins and microelements are an important issue after surgery. Vitamin deficits usually result from absorption-reducing surgeries. The exception is the deficiency of thiamine, which is likely to occur after procedures increasing the risk of vomiting. Hence the replenishment of this vitamin should be a routine. Also vitamin D deficiency, which is common, especially in obese people, should be marked and possibly completed before surgery. After the surgery the aim should be to maintain the concentration of metabolite 25(OH)D more at the level over 30 ng/dl. This may require the administration of doses of 50,000 units 3 times a week or even every day. If the treatment proves ineffective, there may be need of Calcitriol. Calcium is best administered in the form of citrate, in doses of 1,200-1,500 mg/d. After 2 years of treatment densitometric scanning should be performed and possible osteoporosis treated with intravenous bisphosphonates so as to avoid any adverse effect on the mucous membranes of the digestive tract. Iron deficiency affects 30% of menstruating women after RYGB surgeries as a result of malabsorption and often a decreased red meat supply. The shortage should be supplemented with oral medicine, and that fails – intravenous one.

Patients after RYGB surgery often suffer from vitamin B_{12} deficiency, which occurs in about 30% cases without supplementation and 5 years after surgery it affects half of the patients. It usually results from a low red meat supply, decrease in the production of the internal factor (IF) and hypochlorhydria in the digestive tract. Because it causes serious neurological symptoms, it should be supplemented in all patients after RYGB bucally (500-1,000 ug/d), sublingually (500 ug/d), nasally (500 ug/d) or intramuscularly (100 ug/d). Post-surgical shortages can include selenium, zinc and copper, but their routine determination after the procedure is not recommended.

Bariatric surgeries are the primary way of interventional treatment of obesity, obesity-related diabetes and other metabolic disorders. However, other, less invasive therapeutic methods are still being searched for. Some of them were presented at the recent 3rd World Congress of Intervention Treatment of Diabetes in September in London. One such method is gastric balloon of an innovative technology, which does not require a surgical intervention to insert and biodegrades after 4 months without the necessity to remove. The balloon is swallowed by the patient and filled with gas in the stomach. It is designed for a rapid weight reduction by inducing a sense of filling the stomach and reducing appetite. Currently clinical trials with such a balloon being carried out, and their results will have been known by the end of 2015.

Similar studies are conducted in order to evaluate a EndoBarrier technique, in which a special membrane which insulates mucous membrane from the intestinal lumen is placed with an endoscope in the upper section of the digestive tract. The membrane hinders digestion and absorption of food. The system is aimed at obese people suffering from diabetes which ceases to be well-controlled with diet and medications. The first encouraging results with a small number of adverse reactions (nausea, pain, and sometimes infections of the spot the membrane was placed in), the method is now available commercially in many countries.

Another tested procedure is now Revita Duodenal Mucosla Resurfacing (DMR). The technique involves non-invasive, thermal (low temperature) the separation of the outer surface of the mucous membrane layer from the submucosa of the duodenum and upper gas-

trointestinal tract, resulting in an significant impairment of digestion and absorption. The method is also designed for obese patients with type 2, insulin-resistant diabetes. As the first test results the treatment is very well tolerated and results in a lowering of HbA1c concentration by up to 2% after 3 months. Beneficial effects persist for up to 6 months of observation.

Yet another novel way to combat obesity and improve glycemic control is gastric contractility modulation (GCM). The system is composed of a pulse generator placed in the subcutaneous tissue of the abdomen and connected with 3 pairs of electrodes to the surroundings of stomach cardia and fundus (laparoscopic surgery under general anesthesia). The device recognizes the natural electrical activity of the stomach when feeding begins and automatically turns on the therapeutic impulsation (i.e. pulses synchronized with the internal activity of the stomach) that increases the natural activity and as a result the organ shrinkage. As a result, there is increased activity in afferent vagus nerve fibres which conduct signals from the stomach to the brain's appetite-regulating centres in order to cause the feeling of satiety and reduce the amount of food consumed. Until now the system has been applied in about 270 patients worldwide, and the longest observations exceed seven years. As proved by the research already published, the treatment is safe, with 85% of patient achieving a significant decrease in body weight and improvement in glycemic control. HbA1c reduction of 1.0-1.5% was reported for 83% of the patients (28). More importantly, the system requires a minimum compliance of the patient and is free from adverse effects on life quality. It seems that it may be targeted at the patients with type 2 diabetes who are overweight/obese and may offer an alternative for incretine medicine or insulin. It can also be substituted for bariatric surgery if patients are refuse to consent on such treatment or they do not fully meet the eligibility criteria for its implementation.

CONCLUSIONS

In conclusion, obesity is known to be linked to numerous metabolic disorders which lead to accelerated atherosclerosis and increase the risk of cardiovascular diseases. Their final, dramatic effect is often a heart attack and a stroke. Bariatric (metabolic) surgery is the most effective method, enabling the patient to obtain a full remission of diabetes, reduce insulin resistance and improve dyslipidemia. As a result, it is often possible to completely stop medicine therapies including insulin. In practice, the daily success of treatment depends not only on the surgeon, but also on the family doctor or endocrinologist (diabetologist) who is responsible for the qualification and preparation for the surgery and takes post-surgery care of the patient, paying particular attention to the recognition and replenishment of nutrients, vitamins and trace elements deficiencies.

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