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ETHICAL CONSIDERATIONS IN BARIATRIC SURGERY IN A DEVELOPING COUNTRY

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Abstract

Background and aims. *Obesity is the fastest growing health problem worldwide. Ethical issues linked to obesity are numerous and still under debate even in countries with a long history in obesity treatment.*

Methods. *From 2007 to 2015 we performed several types of bariatric surgical approaches on 250 patients with an average body mass index (BMI) of 42. The age range was 12-64 years. No death was recorded. Direct or phone contact was possible with 90% of them during follow-up. Starting from a specific question based approach in ethics we present aspects regarding obesity surgery in Romania. Patients' safety, informed consent, cost cover, the role of bariatric surgery in children and bariatric surgeons' training are discussed.*

Results. *Co-morbidities improved or even disappeared in 90% of our patients. Informed consent is a major problem, due to the lack of public knowledge necessary. The private system in Romania offers bariatric surgery at lower prices than Western Europe but is still out of reach for a person with an average income. Lack of maturity and disharmonic family relations raise a series of challenges in assessing the best interest of children and adolescents. Ethics committees, which operate according to well-defined processes, are more and more active in universities and research centers in Romania, checking that methods and performance of scientific studies meet adequate standards.*

Conclusions. *A detailed informed consent, thorough preoperative patient assessment and method selection are mandatory for good results in obesity surgery. Insufficient financial resources combined with the long time necessary to acquire the expertise for laparoscopic bariatric surgery may represent an additional pressure on both physicians and patients.*

Keywords: bariatric surgery; medical ethics; informed consent

Statistics show that one-third (34%) of the Romanian population is overweight, and about a quarter (20%) suffer from obesity, according to a study published by the most experienced Romanian medical center for obesity treatment [1].

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We attempted to present the viewpoints and highlight specific aspects regarding obesity and its management in Romania. This may be an important step in identifying arguments that health professionals and decision making authorities may need to take into account regarding the optimal management of obesity in our country. From 2007 to 2015 we performed several types of bariatric surgical operations on 250 patients with an average body mass index

(BMI) of 42. The age range was 12-64 years. No death was recorded. Direct or phone contact was possible with 90% of them during follow-up.

Starting from a question based approach in ethics we selected several problems we considered relevant for moral issues related to bariatric surgery [2].

Q1: Is bariatric surgery a safe and effective method to treat obesity?

The goal of bariatric surgery is to improve the quality of life, both from the objective and subjective point of view. A variety of endpoints are reported in studies, beginning with weight loss, normalization of glycemia, blood pressure etc. Others, like changes in levels of microelements, bone minerals, density and fracture risk [3], are partly still unknown. Patients should have a say in decisions on endpoints but most of them are lured by the advocated advantages and pay little, if no attention, to the fact that for some procedures long term results are not available yet.

Most of our patients (95%) recorded a weight loss of at least 25% of excess body weight. The worst results were in situations where we had to remove the adjustable gastric ring, with 90% of the patients returning to at least the initial weight.

Some forms of bariatric surgery may change the eating habits in ways not entirely explainable. Many of our patients with sleeve gastrectomies experience disgust for fatty meals or sweets, favorite foods before surgery. Some of them even mentioned that food seems tasteless and unattractive. Co-morbidities improved or even disappeared in 90% of our patients. The quality of life improvement, measured with specific tools [4] was considered very good by 65% and good by 30% of our patients.

Q2: Is the information given to the patient of minimal quality?

Regarding the informed consent, a major problem is the lack of general knowledge necessary to understand basic information about bariatric surgery. The low educational level may allow only a partial comprehension of the benefits and risks of surgery leading to unrealistic expectations and poor decision making [5], challenging the informed consent and resulting in potential litigation.

The limit between information and marketing may be crossed in several ways. The tendency to use the term "obesity surgery" instead of "bariatric" or "metabolic" surgery has a strong marketing background. The pressure is put mostly by physicians actively promoting "special offers" from private hospitals.

Studies showed that patients undergoing bariatric surgery do not remember information on potential complications provided to them before surgery [6]. This idea is concordant with our experience showing that an average person can assimilate a limited amount of information in one session.

In order to allow a stratified, thorough information we usually invite our patient to an informal meeting, accompanied by a family member, where information is delivered in a dialogue continued by written details covering approximately 500 words and drawings depicting the surgical procedure. We allow the patient to read the information then encourage both patients and family members to ask questions. Unfortunately in most cases questions are linked more to price and short term results than complications and eating discipline. When complications are detailed, simple words must replace medical terms. Some of them find it difficult to understand the meaning of percentages so, for instance, instead of 5% we usually use the formula "one in 20 patients".

In rare cases [5] the patients did not want their next of kin to be informed that they will undergo a surgical procedure. One patient hid the real type of operation from his family. As a direct consequence some of the family members were misled and thought that the cause of weight loss could be some consumptive disease.

Internet information on bariatric treatment is of variable content and quality, nevertheless patients tend to accept and valorize anecdotic information found in forums.

Risk assessment based on the surgeon's experience and the institution's procedural volume [7] is seldom offered during the informed consent. Although our written informed consent mentions every possible complication, we also detail to our patients the complications we have encountered in our personal experience.

It is demonstrated that a proportion of bariatric surgery candidates have psychological/psychosocial burden [8] which may lead to acceptance of bariatric surgery at any cost, from both financial and medical point of view. Our opinion, formed by contact with several hundred candidates for bariatric surgery, is that the most traumatized are those who experienced childhood obesity and its consequences. The most relaxed are former athletes who gained weight after retiring.

Some guidelines specifically ask for a psychological assessment prior to surgery. We had to turn down several patients with obvious psychiatric problems, most of them being only overweight or with 1st degree obesity. In our series we had a patient that threatened with suicide because of persisting vomiting the first postoperative week after gastric plication.

The figures claiming that up to 80% of candidates for bariatric surgery have psychiatric disorders [8] are certainly much higher than those encountered in our experience. These patients will probably find it difficult to observe the dietary restrictions and the postoperative lack of alimentary discipline may lead to a disappointing weight loss, morbidity or even death.

Q3. Do the implied interests ensure the appropriate procedure selection?

Regarding the interests implied leading to patient and procedure election, the variables that have to be taken into account are numerous.

An important issue is the inclusion criteria and their adaptation in time. It is still unclear who should set the limits with respect to patient BMI, age, family history of obesity and associated diseases. The guidelines still in use were established in the early `90s in USA [9]. Variations regarding the obesity type, race, age, co-morbidities were suggested but not always applied. In our country the limits are more or less self-imposed, especially in private hospitals. We respected the guidelines but adapted them to recent published papers, especially for type 2 diabetes.

It has been demonstrated that bariatric surgery is effective in improving diabetes. However, the choice for optimal moment for surgery is not endorsed by a consensus. Some even advocate that metabolic surgery should be used for the prevention of type 2 diabetes in obese asymptomatic persons after attempts with diet, behavioral changes and drug regime have failed [2].

The variability of procedures also appears to have substantial moral consequences. The choice of a certain procedure should be made by a multidisciplinary team being able to perform all the approved procedures. Unfortunately, professionals and patients have only interests that may go only partly in the same direction. The bariatric environment in our country is regulated only by the conscience and technical skill of the surgeon. Conflicts of interest may arise as surgeons or their employers are stimulated by commercial companies providing products for bariatric surgery.

The patient should not be advised to choose a procedure because the incision is smaller or restricted to a port, or because it may be cheaper or result in a shorter hospital stay [10].

Handling a limited variety of procedures may expose patients to an unsuitable type of operation. Many centers in Romania are not able to offer the laparoscopic gastric by-pass on a regular basis. Another limit may be the lack of specialized equipment for very heavy patients. In these situations patients have to be referred to an appropriate bariatric center. Accepting the limits regarding patients and types of procedures should be a proof of sound judgment for smaller teams. We do not master the gastric by-pass, therefore we refer the patients with a BMI over 55 to a more experienced center.

Patients are active on the forums on internet and their pressure may shift the selection of procedures towards more cheap or "fashionable" ones. We prevent the patients when they wish for an unsuitable procedure and do not accept under any circumstance to perform an unnecessary or obsolete technique.

A very serious ethical problem arises from the general economic problem in which a physician in a situation of diminished income may create an artificial demand for his services [11]. Regarding bariatric surgery, the selection of patients, technique or supplying company may suffer a variable degree of subjective influence.

Thorough preoperative assessment follows after the informed consent of the selected bariatric surgery candidate. The preoperative assessment and preparation has reached a high degree of complexity. Psychosocial evaluation is compulsory prior to bariatric surgery [12]. For the last 4 years we have been recommending psychological testing to all our patients.

Behaviorally induced weight loss is a mandatory step in our presurgical preparation. Usually, we consider that a loss of 15% excess body weight is sufficient for improving the quality of a fatty liver. We use this test to check the self-discipline and compliance. Those who do not manage to pass the test usually obtain mediocre results after bariatric surgery due to a high intake of sweets, nuts or other high calorie foods [13].

We are not yet able to offer presurgical courses which yield better long term results by stimulating lifestyle changes [14].

Q4: Who should cover the costs for bariatric surgery?

Even in wealthy countries this problem is not completely solved. The choice for surgical treatment has to be followed by the selection of the appropriate type of operation. As long as the procedure is only partly covered by the healthcare system the patient will be influenced, at best, by the marketing policies and by the price of a certain procedure.

A Health Technology Assessment performed in Finland concluded that bariatric surgery is effective, cost-effective, and probably cost-saving, but most importantly it did not identify any ethical arguments against bariatric surgical procedures [15].

Bariatric surgery per se is costly, but it saves and offers a longer and better life for a properly selected group of patients. Substantial inequalities in benefiting from bariatric surgery have causes linked to both cultural and income differences. Until recently, obesity was regarded as a sign of prosperity, especially in rural areas or in some ethnic communities in Romania. Women have the tendency to consider the physical aspect more important than men. This situation reaches its peak in USA where 85%–90% of operations are performed on white women with higher income levels [16]. We have noticed also that women's attitude in trying to change their life as an obese person is more courageous and active than in men.

The private system in Romania offers bariatric surgery at lower prices than in Western Europe but is still out of reach for a person with average income.

Too strict inclusion criteria and guidelines,

unbalanced advertisement, and discrimination of gender, fitness, age and ethnicity may lead to an unjust distribution of bariatric surgery [2].

Another important issue is medical tourism in bariatric surgery. The main cause is obviously the costs. Limitations regarding some intensely marketed techniques like gastric plication contribute to the fact that obese patients seek surgical treatment in countries with a more permissive legislation [17]. We operated a few Romanian citizens living abroad but a 30 day postoperative period of close follow-up was mandatory before their return at home.

A direct problem linked to the healthcare system covering bariatric surgery costs is that public opinion has the tendency to consider obesity self-inflected and overweight people should pay for bariatric surgery. Some anti-obesity campaigns use stigmatization of obese individuals as a public health strategy [18]. This is supported by the argument that excessive weight is the consequence of choices for which the individual bears full responsibility [15].

Q5: Is bariatric surgery directly applicable in children and adolescents?

Bariatric surgery in children and adolescents has several specific issues that have to be underlined. Specialists have to give adequate advice both to patients and parents so the appropriate decisions can be taken [19]. There is a consensus that bariatric surgery in children and adolescents should be performed in specialized, high volume centers.

Children and adolescents are still developing, both physically and mentally and they may have reduced competency to consent [20].

A young patient may be considered a candidate for surgery if conservative means yielded no results and if the risk/benefit profile is favorable for surgery [21].

Lack of maturity and disharmonic family relations pose a series of challenges in assessing the best interest of children and adolescents [20].

Parents and adolescents who consider obesity as something that they can directly influence tend to be more in favor of non-surgical treatment [22].

On the other hand minors wanting surgery are less able to make an autonomous decision than minors who do not wish to undergo surgery [23].

Q6: Which is the safest system for a bariatric surgeons training?

Credentialing of surgeons and the information for obesity professionals may vary in different countries and healthcare systems. Professional societies in Romania organize periodical symposia, workshops and trainings in the field of bariatric surgery but can, at best, establish recommendations regarding competence, patient and operation selection. A national register is still a desire far from reality despite individual and group effort.

The mass media presentation of obesity as an increasing health problem has created a sense of urgency about the need for effective treatments. Offering early visible results with apparently no effort and low risk bariatric surgery has gained wide acceptance. On this momentum the tendency to exempt some of these operations from the rigorous regulatory scrutiny applied to drugs and surgical devices has caused alarm in medical circles [24]. Fortunately, ethics committees, which operate according to well-defined processes, are more and more active in universities and research centers in Romania checking that methods and execution of scientific studies meet adequate standards.

A large part of surgical innovation is the medical equipment companies generating pressure towards promoting devices or surgical procedures - robotic surgery may well be one of them. In obesity surgery more than in other fields of surgery there is a tendency to promote new and not validated procedures before the outcomes are fully explored, or re-discovered techniques that skipped steps on their way to clinical approval. Industry pressure, academic ambitions, patient desire for safer and cheaper procedures or the position of expert in a new field may be the causes of this distortion [25].

Bariatric surgery has the potential to cause harm not so much on short term but more from the point of view of uncertainties regarding efficacy, the need for revisional surgery or irreversibility of surgery [24].

The number of bariatric operations is increasing every year without being able to cover the needs. Insufficient financial resources combined with the long duration necessary to acquire the expertise for laparoscopic bariatric surgery will further limit the access, at least for the 10 years to come, leading to rationing. An important ethical issue is that rationing of bariatric surgery should observe the general principles for rationing access to treatment of any disease.

References

1. Clinica Ponderas. Comunicat de presa. Available from: http://www.ponderas.ro/ro/media/comunitate-de-presa/comunicat-de-presa-1/obezitatea-in-romania/

2. Hofmann B, Hjelmesæth J, Søvik TT. Moral challenges with surgical treatment of type 2 diabetes. J Diabetes Complications. 2013;27(6):597-603.

3. Lautz D, Halperin F, Goebel-Fabbri A, Goldfine AB. The great debate: medicine or surgery: what is best for the patient with type 2 diabetes? Diabetes Care. 2011;34(3):763-770.

4. Moorehead MK, Ardelt-Gattinger E, Lechner H, Oria HE. The validation of the Moorehead-Ardelt Quality of Life Questionnaire II. Obes Surg. 2003;13:684-692.

5. Wee CC, Jones DB, Davis RB, Bourland AC, Hamel MB. Understanding patients' value of weight loss and expectations for bariatric surgery. Obes Surg. 2006;16(4):496-500.

6. Madan AK, Tichansky DS, Taddeucci RJ. Postoperative laparoscopic bariatric surgery patients do not remember potential complications. Obes Surg. 2007;17(7):885-888.

7. Ballantyne GH, Belsley S, Stephens D, Saunders JK, Trivedi A, Ewing DR, et al. Bariatric surgery: low mortality at a high-volume center. Obes Surg. 2008;18(6):660-667.
8. Sarwer DB, Cohn NI, Gibbons LM, Magee L, Crerand CE, Raper SE, et al. Psychiatric diagnoses and psychiatric treatment among bariatric surgery candidates. Obes Surg. 2004;14(9):1148-1156.
9. NIH conference. Gastrointestinal surgery for severe obesity. Consensus Development Conference Panel. Ann Intern Med. 1991;115:956–961.
10. Willbanks OL. A plea for professionalism. Obes Surg. 1999;9(2):210.
11. Macgregor AM, Macgregor CC. Economic theory and physician behavior in bariatric surgery. Obes Surg. 2000;10:4-6.
12. Rouleau CR, Rash JA, Mothersill KJ. Ethical issues in the psychosocial assessment of bariatric surgery candidates. J Health Psychol. 2016;21(7):1457-1471.
13. Glenn NM, Raine KD, Spence JC. Mandatory weight loss during the wait for bariatric surgery. Qual Health Res. 2015;25(1):51-61.
14. Knutsen IR, Terragni L, Foss C. Morbidly obese patients and lifestyle change: constructing ethical selves. Nurs Inq. 2011;18(4):348-358.
15. Saarni SI, Anttila H, Saarni SE, Mustajoki P, Koivukangas V, Ikonen TS, et al. Ethical issues of obesity surgery--a health technology assessment. Obes Surg. 2011;21(9):1469-1476.
16. Flum DR, Kwon S, MacLeod K, Wang B, Alfonso-Cristancho R, Garrison LP, et al. The use, safety and cost of bariatric surgery before and after Medicare's national coverage decision. Ann Surg. 2011;254(6):860-865.
17. Birch DW, Vu L, Karmali S, Stoklossa CJ, Sharma AM. Medical tourism in bariatric surgery. Am J Surg. 2010;199(5):604-608.
18. Vartanian LR, Smyth JM. Primum non nocere: obesity stigma and public health. J Bioeth Inq. 2013;10(1):49-57.
19. Mărginean O, Brînzaniuc K, Mărginean C. Ethical Considerations in the Child's Obesity. Revista Română de Bioetică. 2013;11(4):12-20.
20. Hofmann B. Bariatric surgery for obese children and adolescents: a review of the moral challenges. BMC Med Ethics. 2013 Apr 30;14:18. doi: 10.1186/1472-6939-14-18.
21. Caniano DA. Ethical issues in pediatric bariatric surgery. Semin Pediatr Surg. 2009;18(3):186-192.
22. van Geelen SM, Bolt IL, van der Baan-Slootweg OH, van Summeren MJ. The controversy over pediatric bariatric surgery: an explorative study on attitudes and normative beliefs of specialists, parents, and adolescents with obesity. J Bioeth Inq. 2013;10(2):227-237.
23. Bolt IL, van Summeren MJ. Competence assessment in minors, illustrated by the case of bariatric surgery for morbidly obese children. Best Pract Res Clin Gastroenterol. 2014;28(2):293-302.
24. Dixon JB, Logue J, Komesaroff PA. Promises and ethical pitfalls of surgical innovation: the case of bariatric surgery. Obes Surg. 2013;23(10):1698-1702.
25. Shikora SA. A call for maintaining ethical behavior in bariatric surgery. Obes Surg. 2012;22(6):849-850.