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BREAST IMPLANTS MALPOSITION PREVENTION AFTER AESTHETIC AUGMENTATION MAMMOPLASTY

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Prevention of breast implant malposition (BIM) after submuscular augmentation mammoplasty (SAMP) for hypomastia is an actual problem, as 4.7–5.2 % of women after primary SAMP and approximately 10 % after repeated SAMP require revision surgery due to this complication.

The aim. To determine the effectiveness of prevention of BIM after SAMP by choosing the implant volume depending on the physique of women.

Materials and methods. In 112 women, the choice of implant volume for SAMP was carried out in accordance with the High Five approach – the comparison group (Group C), in 46 women according to the developed algorithm – the main group (Group M). The algorithm took into account the risk of BIM in women of different physique depending on the implant volume. If a woman insisted on having a larger implant than was calculated, an additional internal bra was created.

One year after SAMP, the amount of BIM was assessed according to the developed methodology, according to which BIM was characterised by the percentage increase in the area of the neo-osseous in relation to the area of the prosthesis. The following categories of BIM were distinguished: absent (insignificant) 1.5 % to 6.4 %, mild – 6.5 % to 10.4 %, moderate – 10.5 % to 20.0 %, significant – more than 20 %. Women's body type was assessed by the Pignet's Index, which distinguished three categories: strong <16, medium 16–25, and weak 26–35. In group M, the maximum possible implant volume with a low risk of BIM was considered to be for women with a weak physique – 360 ml, medium – 430 ml, strong – 650 ml.

Results The mean percentage of BIM was significantly lower in group M (7.2±1.8 %) compared to group C (9.1±6.1 %), p=0.036. At the same time, the incidence of significant BIM significantly decreased from 18 (16.1 %) in group C to 2 (4.3 %) in group M, p=0.044. Moreover, patients in group M had BIM that could be classified as moderate, while in group P, 9 (50 %) women had moderate and 9 significant BIM. In the case of additional creation of an internal bra, there was no significant BIM in any case, the average value of this indicator was 6.3 ± 1.6 % (no or mild BIM).

Conclusion. The developed personalised approach to the choice of implant volume, taking into account the physique of women, significantly improves the results of SAMP and prevents significant BIM **Keywords:** Breast implants malposition, prevention, women's physique, implant volume

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1. Introduction

Breast implant malposition (BIM) from the initial site of implantation after augmentation mammoplasty (AMP) is an expected situation. There is usually a slight BIM malposition (MBIM) when women do not insist on repeat corrective surgery. But 4.7 %-5.2 % of women after primary AMP [1, 2] and approximately 10 % after repeated [3, 4] need it. Given that, according to some data, MBIM can occur in 94 % of women within 7 years after SAMP [5], prevention of this complication becomes important. It is obvious that the prevention of MBIM should be aimed at eliminating or reducing the influence of established risk factors. Recently, the probability of malposition of breast implants one year after augmentation mammoplasty was determined in women with different body types, depending on the volume of the implant [6]. However, studies evaluating the effectiveness of MBIM prevention through selection of the appropriate implant volume are currently lacking.

The aim of the work. To determine the effectiveness of prevention of malposition of mammary gland implants after cosmetic augmentation mammoplasty by choosing the volume of the implant depending on the physique of women.

2. Materials and methods

The study included 158 women who underwent submuscular AMP (SAMP) in a double plane from a submammary access due to hypomastia in the period from 2020 to 2022 based on the Bogomolets National Medical University (KNP "Oleksandrivska Clinical Hospital of Kyiv" and the medical center "Cititdoctor").

All patients were implanted with round prostheses with a smooth surface submuscularly according to the standard technique. The main condition for prosthesis implantation was the location of the center of the prosthesis sphere with the point of intersection of the midclavicular line, the length of which was 22 cm for women over 175 cm tall, 21.5 cm for women 165–174 cm tall, and 21 cm for women below 165 cm tall with a line drawn from the jugular fossa of similar length. This point of intersection of the lines corresponded to the projection of the nipple on the chest wall when the patient was standing with her arms down. The area of the base of the implants had to ensure an intramammary distance of 3 cm.

One year after SAMP, the amount of malposition of MBIM implants was assessed according to the developed method [7]. According to this method, MBIM was characterized by the percentage of the increase in the area of the unoxidized area in relation to the area of the prosthesis and was calculated according to the formula:

(the area of neo-osmosis - the area of the implant) / the area of the implant.

Women of group O were classified as those in whom the unoxygenated area of at least one implant increased by more than 10.4 % in relation to the area of the implant [7]. Significant MBIM included moderate with MBIM values of 10.4 %-20.0 % and significant with MBIM values greater than 20 %.

Body type of women was assessed according to the Pignet index:

$$I=L-(P+T)$$

where I is the Pignet index; L - body length, cm, P – body weight, kg; T is the circumference of the chest during exhalation, cm.

Usually, the body type according to the Pignet index has the following categories: very strong <10, strong - 10-15, good - 16-20, average - 21-25, weak -26-30, very weak -31-35 [8]. In our study, we saw three categories of women's physique depending on the Pignet index: strong < 16, medium 16–25, weak 26-35.

The women were divided into two groups. One group (comparison group - group C) included 112 women in whom the selection of the implant volume was carried out according to the High Five approach described by Tebbetts J.B. and Adams W. P. [9], however, also considered the wishes of women. The other group included 46 women (the main group - group M), in which the choice of implant volume was based on the

data we obtained earlier [6]. According to which, the probability of MBIM one year after submuscular augmentation mammoplasty depends on the woman's physique and the volume of the implant. In women with a strong physique, the probability of significant malposition (more than 50 %) occurs in the case of implantation of prostheses with a volume of more than 650 ml, in women with an average physique - in the case of 430 ml, in women with a weak physique - in the case of 360 ml [6]. That is, to prevent MBIM, women were recommended implants, the volume of which should not exceed the specified critical value for their physique. If the woman insisted on installing a larger implant, the pockets were reinforced with GalaFLEX mesh, creating a so-called internal bra. The mesh covered at least the lower half of the implant, but below the nipple projection. The mesh was fixed from the medial to the lateral border of the pocket along the lower edge of the IMF by suturing it to Scarpa's fascia and sometimes to the periosteum of the rib using a 2–0 Vicryl suture with 4-6 knotted sutures.

The study was conducted in accordance with the Helsinki Declaration of Ethics [10]. The research protocol was approved by the Ethics Committee of the Bogomolets National Medical University (protocol No. 139 of November 24, 2020). Informed consent was obtained from all study participants.

Statistical processing of the obtained data was carried out using the statistical package IBM SPPS Statistics 22. Descriptive statistics, cluster analysis, linear analysis were performed. The comparison of the mean values of the variables was carried out using parametric (calculation of the Student's t-test) and non-parametric (calculation of the Mann-Whitney U-test) methods depending on their type and nature of distribution. Comparative assessment of the relations of parts of variables expressed in nominal or ordinary scales was performed using the Pearson χ^2 test. The probability of occurrence of an event was determined using binary logistic regression. The null hypothesis of equality of variables was rejected at p<0.05.

3. Research results

in age, average BMI, frequency of pregnancy, breast feeding, Pignet index and physique, Table 1.

Characterist	tics of research groups							
Indicator	Group M n=112	Group C n=46	р					
Age (years) M±SD (min-max)	34.1±6.7 (19–51)	33.2±7.4 (23–50)	0.456					
BMI (kg/ m sq) M±SD (min-max)	20.4±1.8 (17.4–25.3)	20.7±1.9 (18–25.7)	0.491					
Pregnancy, n (%)	78 (69.6)	35 (76.1)	0.415					
Breast feeding, n (%)	75 (67.0)	33 (71.7)	0.558					
Pignet index M±SD (min-max)	18.2±6.7 (8–31)	18.9±5.9 (8–31)	0.392					
Stature:								
strong, n (%)	53 (47.3)	15 (32.9)						
medium, n (%)	34 (30.4)	21 (45.7)	0.147					
weak, n (%)	25 (22.3)	10 (21.7)						

Women of both groups did not statistically differ

On average, women in group M used implants with a larger volume of 450.2 ± 88.4 ml compared to group C - 410.3 ± 95.9 ml, p=0.001, Fig. 1.

This is due to the fact that in group M in women of each body type, we selected the volume of implants, which is close to the acceptable volumes defined by us earlier, with a low probability of significant MBIM [6]. In 11 (23.9 %) women of the M group who insisted on installing implants, the volume of which exceeded the critical value for the fit of the body, the pockets were reinforced with GalaFLEX mesh, creating a so-called internal bra. This operation was performed on 2 (20.0 %) women with a weak stature, 7 (33.3 %) with medium stature and 2 (13.3 %) with a strong stature, p=0.362, Table 2.



Fig. 1. The percentage of applied breast implants of different volumes in the study groups

Table 2

Freq	uency	y of SAMP	with	reinforcement	of	the im	plant	pocket	with	mesh	in	women	of	different	body	y ty	pes
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				Total					
	W	eak	Medium		Strong		Total		
Reinforcement of the pocket with a mesh	Abs.	%	Abs.	%	Abs.	%	Abs.	%	
Yes	2	20.0	7	33.3	2	13.3	11	23.9	
No	8	80.0	14	66.7	13	86.7	35	76.1	
Total	10	100.0	21	100.0	15	100.0	46	100.0	

One year after SAMP, displacement of the implants from the initial location was noted in all mammary glands. The average percentage increase in the area of non-oxygenated implants and, therefore, the quantitative measure of MBIM (taking into account MBIM in all mammary glands) in group M was smaller compared to group C and was 7.0 ± 1.7 % (from 3.2 % to 16.2 %) versus 7.9 ± 4.5 % (from 1.5 % to 34.5 %), respectively, but did not acquire statistical significance, p=0.060.

At the same time, if we consider the highest values of MBIM in each woman, the difference between the groups in terms of the average MBIM indicator becomes reliable: in group $M - 7.2 \pm 1.8$ %, in group $C - 9.1 \pm 6.1$ %, p = 0.036., Fig. 2, 3.



Fig. 2. Distribution of women by MBIM value in group M



Fig. 3. Distribution of women by MBIM value in group C

Significant MBIM occurred in 20 women: in group M - in 2 (4.3 %), in group C - in 18 (16.1 %), p=0.044, Table 3.

Among women of group C, significant MBIM occurred more often in case of weak and medium stature (p=0.004); in group M in one case in the case of a weak and in one case in the case of a medium stature, Table 4.

Significant MBIM has two categories – moderate and significant. In group C, 9 (50 %) women had moder-

ate and 9 significant MBIM, while in group M there was no case of significant MBIM and 2 women had moderate MBIM. Therefore, in the presence of significant MBIM, its average percentage in the C group was higher -20.6 ± 7.6 % compared to the M group -12.1 ± 0.7 , p=0.140.

In women of group M, who were additionally created with an internal bra, in all cases there was no significant MBIM, the average value of this indicator was 6.3 ± 1.6 %, Fig. 4.

Table 3

	2 0		5	20			
MDIM	Group M		Group	С	Total		
MDIM	Abs.	%	Abs.	%	Abs.	%	
Not significant	44	95.7	94	83.9	138	87.3	
Significant	2	4.3	18	16.1	20	12.7	
Total	46	100.0	112	100.0	158	100.0	

Frequency of significant MBIM one year after SAMP in study groups

Table 4

The frequency of non-significant and significant MBIM depending on the physique of women in the study groups one vear after SAMP

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Group	MDIM		Total		
Group	IVIDIIVI	Weak	Weak Medium		Total
Group C	Non-significant, n (%)	18 (72.0)	25 (73.5)	51 (96.2)	94 (83,9)
Group C	Significant, n (%)	7 (28.0)	9 (26.5)	2 (3.8)	18 (16,1)
	Total	25 (100,0)	34 (100.0)	53 (100.0)	112 (100.0)
Group M	Non-significant, n (%)	10 (90.9)	19 (95.0)	15 (100.0)	44 (95,7)
	Significant, n (%)	1 (9.1)	1 (5.0)	0 (0.0)	2 (4,3)
	Total	11 (100,0)	20 (100.0)	15 (100.0)	46 (100.0)



Fig. 4. Distribution of mammary gland according to the MBIM value in women of group M.

Thus, a personalized approach to choosing the implant volume and determining the feasibility of creating an internal bra in women who are planned for SAMP, considering their body type, ensures a smaller amount of MBIM and prevents the occurrence of significant MBIM.

4. Discussion of research results

In some period after SAMP, malposition of implants of various severity occurs in all mammary glands [11]. In most cases, it is insignificant and does not create cosmetic problems for women. But in 4.7 %-5.2 % of women it becomes significant and requires repeated surgery [1, 2]. Prevention usually consists of several stages: preoperative (thorough preoperative examination, choice of implant) [9, 12], intraoperative (choice of surgical technique [13], including the use of additional materials [14, 15], compliance with maximum atraumaticity of surgical intervention, creation a pocket corresponding to the volume of the implant [16, 17]), postoperative (refrain from massaging the mammary gland, wearing a bra for at least 2–3 months; avoiding sports for 6 weeks, especially those associated with significant movements of the upper body [18, 19]).

One of the key factors in the prevention of MBIM is the selection of an implant of optimal volume, but this issue has not been definitively resolved. It is no coincidence that Adams W. P. Jr, and Mckee D. discovered thirty-three systems for choosing the size of an implant [20]. The problem of choosing an implant to prevent MBIM is closely related to the method of its evaluation. Currently, existing methods of determining the degree of MBIM are based on a qualitative subjective assessment. In the literature, you can find the MBIM severity scores as too low, too high, too medial, too lateral [16], or none, mild, moderate, severe, and very severe [21], or as having occurred or not occurring [22]. Recently, we proposed a method of quantitative assessment of MBIM [7], which made it possible to objectively assess the risk of malposition of different volumes of MBIM implants depending on the type of the patient's physique. In par-

ticular, in women with a strong physique, the probability of significant malposition (over 50 %) occurs in the case of implantation of prostheses with a volume of more than 650 ml, in women with an average physique – in the case of 430 ml, in women with a weak physique - in the case of 360 ml [6]. In our study of women of group M, we relied on these data, and in case of a woman's persistent desire for implants of a larger volume than we suggested, the operation was supplemented by the creation of an internal bra using a mesh. In addition, we followed other generally accepted intraoperative and postoperative preventive measures. A comparison of the results in the main group and the comparison group one year after SAMP showed the feasibility of the specified approach. After all, the average percentage of MBIM was significantly lower in group M - 7.2 \pm 1.8 %, compared to group $C - 9.1 \pm 6.1$ %, p=0.036. At the same time, the frequency of significant MBIM significantly decreased from 18 (16.1 %) in group C to 2 (4.3 %) in group M, p = 0.044. Moreover, group M patients had MBIM, which can be qualified as moderate, while in group P, 9 (50 %) women had moderate and 9 significant MBIM.

In the case of additional creation of an internal bra, there was no significant MBIM in any case, the average value of this indicator was 6.3 ± 1.6 % (absent or mild MBIM). Therefore, the approach we used for the prevention of MBIM after SAMP, although it does not prevent it absolutely, but it turned out to be better than the traditional approach.

Study limitations. The work has certain limitations. Firstly, it concerns only the prevention of malposition of mammary gland implants, which are installed for cosmetic purposes submuscularly in a double plane, however, this technique is currently the most common, and secondly – it does not take into account factors other than the physique of women, which can contribute to malposition of mammary implants glands, although it should be noted that the main group and the comparison group did not differ in terms of the main risk factors and the technique of surgical intervention, thirdly, there was

no objective control of women's compliance with recommendations regarding preventive measures of implant malposition in the postoperative period.

Prospects for further research. The results of prevention of MBIM after primary submuscular augmentation mammoplasty, based on the choice of implant volume depending on the physique of women, have shown effectiveness. It is known that surgical removal of the resulting MBIM is associated with a higher recurrence rate than primary surgery. Therefore, it seems appropriate to determine the effectiveness of this approach for the secondary prevention of MBIM.

5. Conclusions

SAMP performed with the use of implants of a limited maximum volume (for women with a weak build -360 ml, medium -430 ml, strong -650 ml) provides a lower average percentage of the MBIM value of 7.2 ± 1.8 %, compared to the standard approach -9.1 ± 6.1 %, p=0.036 and a lower frequency of clinically significant MBIM 2 (4.3 %) versus 18 (16.1 %), p=0.044.

Additional creation of an internal bra during SAMP is associated with a low mean MBIM value of 6.3 ± 1.6 %.

Conflict of interests

The authors declare that they have no conflict of interest in relation to this research, including financial, personal, authorship, or any other nature that could affect the research and its results presented in this article.

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Data availability

Data will be provided upon reasonable request.

Use of artificial intelligence technologies

The authors confirm that they did not use artificial intelligence technologies when creating the presented work.

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