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The influence of BMI, smoking, and age on vaginal erosions after synthetic mesh repair of pelvic organ prolapses. A multicenter study

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Abstract

Objective. To study the influence of body mass index (BMI), smoking, and age on the risk of vaginal erosions after mesh repair of pelvic prolapses. *Design.* Retrospective study. *Setting.* Three university and community hospitals. *Population and sample.* Patients that underwent mesh correction of prolapses between 2002 and 2007. Excluded were those with stress urinary incontinence, ongoing clinical infections, with a complete antibiotic course in the last six months and with systemic diseases affecting tissue oxygenation. *Methods.* Revision of medical notes. *Main outcome measures.* Risk contributions for age, smoking, and BMI on the occurrence of vaginal erosions. *Results.* Data were collected from 460 patients. Postoperative erosions were present in 7%. BMI greater than 30 conferred a 10.1-fold increase in the risk of developing erosions, smoking a 3.7-fold increase, and age greater than 60 years a 2.2-fold increase. A cut-off value of seven pack years was determined for smoking where the risk associated with light smokers was similar to that of non-smokers. *Conclusions.* BMI, smoking, and age are important risk factors for pelvic organ prolapse surgery. Our data could be used to stratify patients according to their risk so that preventative measures can be taken in high-risk patients.

Key words: *Vaginal erosions, polypropylene mesh, synthetic mesh, vaginal mesh, pelvic organ prolapse, pelvic reconstructive surgery, body mass index, smoking, age, risk factors*

Introduction

In recent years different risk factors have been investigated for the occurrence of postoperative wound infections. The body mass index (BMI) (5–10), age (11–18), and smoking (19–35) were all correlated with this complication. Their effect was particularly noticeable when the final outcome of surgery was dependent to a great degree upon optimal tissue vascularization, for example, when flaps are raised during plastic surgery.

Vaginal erosions are a relatively common complication that may occur when synthetic prostheses are used for the treatment of stress urinary incontinences (SUI) and pelvic floor prolapses (POP) (1,2). A number of risk factors have already been investigated in relation to this complication: the operative technique adopted, implant sizes, specific properties of the sling material, inadequate vaginal tissue coverage, tissue vascularization, infections, and early resumption of sexual activities. These were found to have a direct influence on the rate of vaginal erosions (2–4).

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Synthetic meshes may act as a foreign body in the recipient and give a continuous erosive inflammatory stimulus within tissues. As with other types of surgery, an optimal local trophism is required for a correct wound healing. BMI, age, and smoking could eventually influence the wound healing status and thus impact upon the occurrence of vaginal erosions.

The present study was conducted in order to evaluate the role of these three factors on the occurrence of vaginal erosions. A multicenter retrospective study involving patients who received a mesh-based POP repair was conducted. Data were gathered and analyzed in order to determine whether there was a significant relation between these three variables and vaginal erosions and to estimate the contribution of each to the occurrence of this complication.

Materials and methods

This retrospective study was approved for exemption from obtaining informed consent by the Institutional Ethical Committee, under the provision that patients' data were gathered, analyzed, and reported anonymously. We retrospectively reviewed charts of patients that underwent mesh correction of POP in our institutions (University 'Tor Vergata' and Policlinico Casilino in Rome, S.Francesco D'Assisi Hospital in Olivetro Citra, Salerno, and 'S. Giovanni Evangelista' Hospital, Tivoli, Rome) between January 2002 and January 2007. We excluded from the analysis patients who wanted to preserve their uterus, those affected by SUI (for the requirement of the additional sling), with ongoing clinical infections, that received a complete antibiotic course in the last six months prior to the operation, and with systemic diseases that adversely affect wound healing by impairing tissue oxygenation (cardiovascular diseases, hypertension, and diabetes mellitus). Patients with SUI were diagnosed preoperatively by urodynamic evaluation.

According to standard prophylaxis measures of deep venous thrombosis (DVT), low molecular weight heparin was administered (Enoxaparin 4000 UI S.C.) one hour before the operation along with elastic stockings/mechanical calf compression until complete mobilization was achieved. Infection prophylaxis was administered with antibiotics 10–30 min before the operation.

All patients underwent a concomitant vaginal hysterectomy. During pelvic floor reconstruction, type 1 polypropylene prostheses (Prolift™ and Gynemesh-Soft PS™, Ethicon, Somerville, NJ, USA) were introduced via the anterior or posterior approach (5–7).

Anterior repair

The anterior vaginal wall was infiltrated with a local anesthetic (0.5% lignocaine), and a midline incision was made 2 cm below the external urethral meatus. The bladder was reached by blunt dissection from the vagina and paravescical spaces detected. Two tiny skin incisions were made on the genitor-femoralis fold, at the level of the hymen, and two other incisions more caudally and laterally. A tunneller, with the prosthesis included, was introduced in the obturator foramen and passed through the obturator membrane and obturator internal muscle until it reached the vagina. At this point, the prosthesis was anchored and arms distended. Finally, the anterior vaginal incision was closed with 3/0 absorbable suture.

Posterior repair

The posterior vaginal wall was infiltrated with 0.5% lignocaine. A midline vertical posterior vaginal incision was made; the rectal wall was reached and separated by blunt dissection from the vagina and pararectal spaces detected. Two small skin incisions for each side were made on the glutei, 3 cm posterior and lateral to the anal verge. A tunneller was introduced, with the prosthesis, and passed through the ischiatic fossa and exited on the para-rectal space. The posterior colpotomy was closed with 3/0 absorbable suture. At the end of the procedure, a vaginal pack was inserted and removed on the first postoperative day.

Antibiotics were administered 12 and 48 hours after the operation and DVT prophylaxis continued until complete mobilization. Tramadol or antinflammatory drugs were usually given as analgesia as required by the patient. Patients without complications were discharged home three days after the operation. Outpatient follow-up visits were planned for the 30th postoperative day and after six months unless symptoms or signs developed. Postoperative vaginal erosions were defined on the basis of clinical signs (vaginal mucosa split, mesh exposure, pain, swelling, and purulent drainage) and classified as either superficial or deep (2,8). Superficial erosions were defined as those less than 2 cm in diameter or that only involved the vaginal mucosa with no obvious signs of infection. They were managed by re-suturing the vaginal mucosa under local anesthetic and once the mesh was exposed, by resecting a small piece of it. When signs of local infection were present, or the antibiogram was positive for pathogens, an oral antibiotic course was started. Deep erosions were defined as those greater than 2 cm in diameter, involving tissues deep below the mucosa

and with evident signs of infection. In these cases, patients were re-admitted to the hospital and the mesh removed under general anesthesia. Eight weeks after removal the mesh was reinserted.

The aim of this study was to assess whether the patient's BMI, cigarette smoking, and age were associated with the incidence of vaginal erosions after synthetic mesh correction of POP. The following data were collected from the patients' medical records: age, weight, height, BMI, number of previous vaginal deliveries, previous hysterectomies, associated pathologies, smoking status, number of cigarettes smoked/day, overall years of smoke, operative time, type of repair (anterior, posterior, both), number of catheterization days, postoperative necessity of re-catheterization, complications (vaginal or bladder perforations, hematomas, obstructions, dyspareunia, superficial, and deep vaginal erosions), recurrences, and reoperations. In order to evaluate possible associations between a patient's cigarette smoking habit and the occurrence of vaginal erosions, we adopted the number of pack years according to the National Cancer Institute (NCI) definition (=number of packs smoked per day*number of years as a smoker), as a measure of their smoking history.

Statistical analysis

All data analysis and calculation of sample size were performed using the Statistical Package for the Social Sciences Windows version 13.0 (SPSS, Chicago, Illinois, USA). Descriptive statistics for quantitative continuous variables were the mean and standard deviation after confirmation of normal distribution, otherwise median and range. Normality assumptions have been demonstrated with histograms, Kolmogorov–Smirnov test, and Shapiro–Wilk test. Descriptive statistics for qualitative categorical variables was performed with frequencies.

Comparison for groups homogeneity was performed with the parametric Student's *t*-test or the non-parametric Mann–Whitney test for continuous variables and the chi-squared test or Fisher's exact test for categorical variables (Fisher's if counts were inferior to five). The odds ratio (OR) of BMI and smoking on the occurrence vaginal erosions were calculated. A p-value of less than 0.05 was considered significant.

Results

According to the inclusion and exclusion criteria, a total of 460 patients were selected from among all centers. Demographics and clinical characteristics are summarized in Table I. We recorded 32 vaginal erosions (7%), 18 superficial and 14 deep. Overall, they occurred after a mean of 12 ± 4 days. Superficial erosions occurred after 7 ± 3 days and deep erosions after 27 ± 3 days. All of them occurred along the suture line. No late erosions were recorded. The most common organism isolated from the site of erosion was the *Staphylococcus epidermidis*. No cases of bladder perforation, hematomas, DVT, or pulmonary embolism were observed. Patients were discharged home after 4.3 days (range 3–6). The mean follow-up was 22 months (range 12–48). Twelve recurrences were recorded and all of them were graded as stage 2 according to the POP-Q-system. After questioning, patients refused a reoperation as they were satisfied with the overall results obtained.

Body mass index (BMI)

The z-test and the chi-squared test confirmed that all groups (smokers vs. non-smokers and non-obese vs. obese patients) were homogeneous for age and height (Table I). According to the BMI of patients, we found four (1.5%) patients with erosions in the non-obese group and 28 (15.1%) in the obese group (chi-squared test; $p<0.001$). Superficial erosions occurred in two (0.7%) patients of the non-obese group and 16 (8.6%) of the obese group (chi-squared test; $p<0.001$). Deep erosions occurred in two patients (0.7%) of the non-obese group and in 12 (6.5%) of the obese group (chi-squared test; $p<0.001$). The analysis showed significant differences in the BMI between those patients that developed erosions vs. those erosion-free (34 ± 5 vs. 29 ± 4; t-test: $p<0.05$). No significant differences for BMI were found between patients that developed deep erosions vs. those with superficial erosions (35 ± 6 vs. 33 ± 4; t-test: NS).

Smoking

Twenty-five vaginal erosions occurred in smokers (11%) and seven in non-smokers (3%) (chi-squared test; $p<0.01$). Fourteen superficial erosions occurred in smokers (6%) and four in non-smokers (2%) (chi-squared test; $p<0.05$). Eleven deep erosions occurred in smokers (4.8%) and three in non-smokers (1.3%) (chi-squared test; $p<0.05$). A significant difference between those that developed erosions vs. those erosion-free was identified in all patients for the number of pack years (11.5 (0–32.8) vs. 14.5 (3.5–35.5); Mann–Whitney test: $p<0.05$). Smokers that developed deep erosions had higher values of pack years compared to those with superficial erosions, although this difference was not statistically

Table I. Descriptive statistics. Values were expressed as mean ± standard deviation and frequencies, except for the non-parametric variable ([a]), described with median and range.

		BMI <30 (n=275)		BMI ≥30 (n=185)	
	All patients (n=460)	Smoker (n=134)	Non-smokers (n=141)	Smoker (n=94)	Non-smokers (n=91)
Age (years)	58±9	59±10	59±8	60±10	55±5
Weight (kg)	75±9	71±6	70±6	84±8	79±9
Height (cm)	160±8	164±6	162±7	160±7	152±6
BMI (kg/m^2)	29±4	26±2	26±2	33±3	34±4
Number of pack years[a]	0 (0–36)	11 (0–33)	–	13 (0–36)	–
Vaginal deliveries					
0	30 (7%)	11 (8%)	9 (6%)	6 (6%)	4 (4%)
1	159 (3%)	44 (33%)	55 (39%)	32 (34%)	28 (31%)
2	217 (47%)	63 (47%)	64 (45%)	46 (49%)	44 (48%)
3	49 (11%)	15 (11%)	10 (7%)	10 (11%)	14 (15%)
4	5 (1%)	1 (1%)	3 (2%)	0	1 (1%)
Previous hysterectomy	120 (26%)	31 (23%)	26 (18%)	34 (37%)	29 (32%)
Operative time (min)[a]	88 (80–150)	88 (80–146)	89 (80–150)	87 (80–146)	89 (80–150)
Type of repair:					
Anterior	259 (56%)	76 (57%)	92 (65%)	49 (52%)	42 (46%)
Posterior	113 (25%)	38 (28%)	22 (16%)	28 (30%)	25 (28%)
Total	88 (19%)	20 (15%)	27 (19%)	17 (18%)	24 (26%)
Catheterization days[a]	1 (0–8)	1 (0–7)	1 (0–8)	1 (0–8)	1 (0–7)
Dispareunia	25 (5%)	7 (5%)	9 (6%)	4 (4%)	5 (6%)
Voiding obstructions	10 (2%)	2 (2%)	2 (1%)	4 (4%)	2 (2%)
Re-catheterizations	9 (2%)	2 (2%)	1 (1%)	4 (4%)	2 (2%)
Vaginal erosions:					
Superficial	18 (4%)	2 (2%)	0	12 (13%)	4 (4%)
Deep	14 (3%)	2 (2%)	0	9 (10%)	3 (3%)
Total	32 (7%)	4 (3%)	0	21 (22%)	7 (8%)
Vaginal perforations	6 (1%)	0	3 (2%)	2 (2%)	1 (1%)
Bladder perforations	0	0	0	0	0
Recurrences	12 (3%)	5 (4%)	1 (1%)	0	6 (7%)
Reoperations	19 (4%)	4 (3%)	1 (1%)	9 (10%)	5 (6%)

significant (11.5 (0–35.5) vs. 10.0 (3.5–33.3); Mann–Whitney test: p=NS).

Age

Nineteen vaginal erosions occurred in older patients (≥60 years; 19/184, 10.3%) and 13 in younger patients (<60 years; 13/276, 4.7%; chi-squared test, $p<0.05$). Eleven superficial erosions occurred in older patients (6%) and seven in younger patients (2.5%) (chi-squared test; p=NS). Eight deep erosions occurred in older patients (4.3%) and six in younger patients (2.2%) (chi-squared test; p=NS). A significant difference between those that developed erosions vs. those erosion-free existed in patients of all ages (62±10 years vs. 58±9 years;

Table II. Occurrences of vaginal erosions among group of patients classified according to the various combinations of risk factors.

	Old patients (≥60 years)	Young patients (<60 years)	BMI ≥30	BMI <30	Smokers	Non-smokers
Old patients (≥60 years)	10.3% (19/184)	–	26.6% (17/64)	1.7% (1/120)	13.7% (16/117)	4.5% (3/67)
Young patients (<60 years)	–	4.7% (13/276)	9.1% (11/121)	1.3% (2/155)	8.1% (9/111)	2.4% (4/165)
BMI ≥30	26.6% (17/64)	9.1% (11/121)	15.1% (28/185)	–	22.3% (21/94)	7.7% (7/91)
BMI <30	1.7% (1/120)	1.3% (2/155)	–	1.5% (4/275)	3.0% (4/134)	0% (0/141)
Smokers	13.7% (16/117)	8.1% (9/111)	22.3% (21/94)	3.0% (4/134)	11.0% (25/228)	–
Non-smokers	4.5% (3/67)	2.4% (4/165)	7.7% (7/91)	0% (0/141)	–	3.0% (7/232)

Table III. Odds ratio for the occurrence of vaginal erosions between groups and subgroups. Merged cells means that, within a group (column) the odds ratio are calculated between rows. (∞) = tendency to infinite.

vs.	Old patients ($\geq$60 years)	Young patients ($<$60 years)	BMI $\geq$30	BMI $<$30	Smokers	Non-smokers
Old patients ($\geq$60 years)	–	2.2	2.9	1.3	1.7	1.9
Young patients ($<$60 years)	2.2	–				
BMI $\geq$30	15.6	7.0	–	10.1	7.4	(∞)
BMI $<$30			10.1	–		
Smokers	3.0	3.4	2.9	(∞)	–	3.7
Non-smokers					3.7	–

Student's *t*-test: $p < 0.05$). No significant differences were observed for age between patients that developed deep erosions vs. those with superficial erosions (66 (46–75) vs. 64 (42–75); Mann–Whitney test: p = NS).

Combination of risk factors

In all patients, the analysis of BMI (obese vs. non-obese) and cigarette smoking (smokers vs. non-smokers), BMI (obese vs. non-obese) and age (old $\geq$60 years vs. young patients $<$60 years), age (adults vs. young patients) and cigarette smoking (smokers vs. non-smokers) yielded four subgroups for the occurrence of vaginal erosions and OR. Incidences of vaginal erosions and OR among groups and subgroups of patients are described in Tables II and III and in Figures 1–3.

Cut-off values of seven pack years for smoking and of 60 years for age were determined with the Received Operating Curves (ROC) curves (Table IV, Figure 4). For the pack year's cut-off, the area under the curve (AUC) corresponded to 0.715, with a sensitivity of 0.75 and a specificity of 0.65. For the age cut-off, the AUC corresponded to 0.618, with a sensitivity of 0.59 and a specificity of 0.61. For the obesity cut-off (BMI = 30), the AUC corresponded to 0.787, with a sensitivity of 0.87 and a specificity of 0.63. In heavy smokers ($\geq$7 pack years) the incidence in obese patients was 26.4% (19/72), and in non-obese of 4.2% (4/96), with an OR of 6.3. In light smokers ($<$7 pack years) and non-smokers, the incidence in obese patients was 8.0% (9/113) and in non-obese 0% (0/179). In heavy smokers the incidence in adult patients was 16.3% (15/92), and in young patients of 11.3% (9/80), with an OR of 1.4. In light smokers and non-smokers, the incidence in adult patients was 4.3% (4/92) and in young patients 2.0% (4/196), with an OR of 2.1.

Discussion

Few randomized controlled trials explored the use of synthetic mesh in pelvic reconstructive surgery. Most

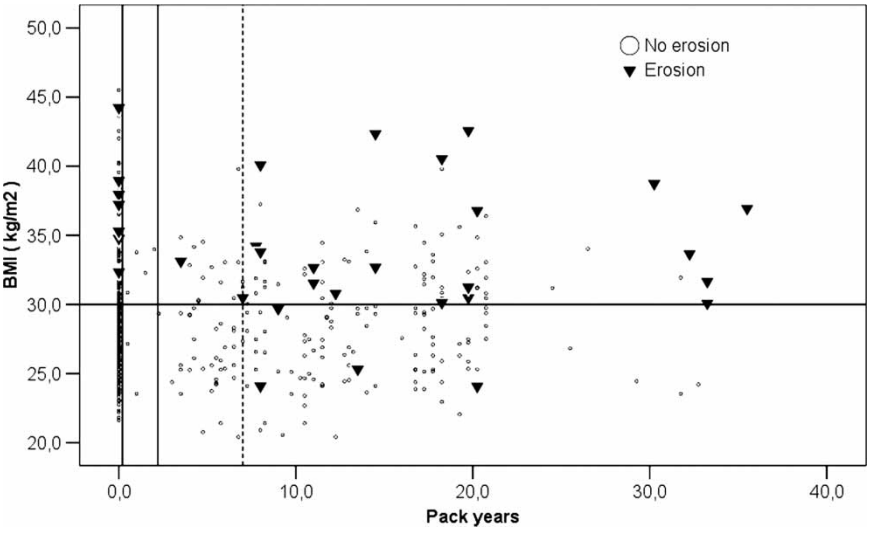

Figure 1. Scatter plot showing the BMI (non-obese and obese patients) vs. pack years for the occurrence of vaginal erosions. Vertical continuous line: cut-off between smokers and non-smokers. Vertical dot line: cut-off between light and heavy smokers (seven pack years). Horizontal line: cut-off between obese and non-obese patients (BMI = 30).

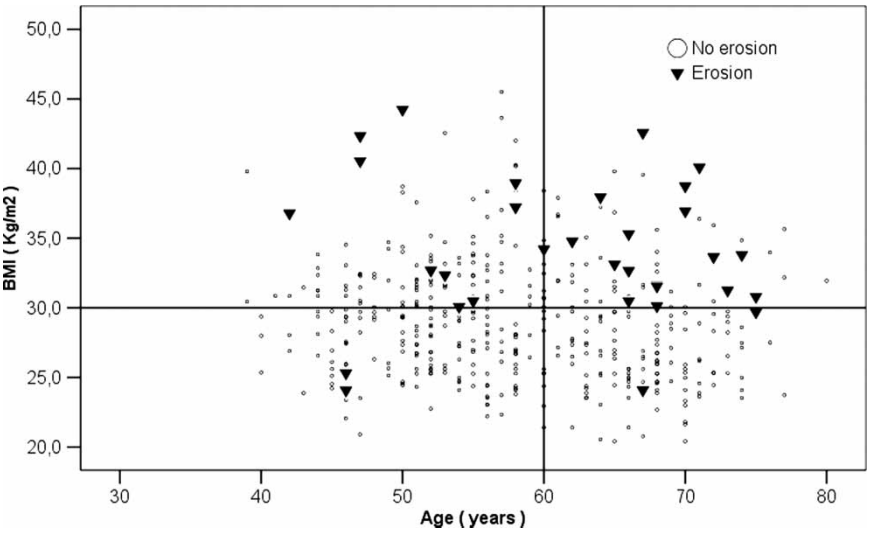

Figure 2. Scatter plot showing the BMI (non-obese and obese patients) vs. age for the occurrence of vaginal erosions. Vertical line: cut-off between adult patients (≥60 years) and young patients (<60 years). Horizontal line: cut-off between obese and non-obese patients (BMI = 30).

of the reported studies are retrospective series, which are difficult to compare because of variations in methodology, type of synthetic mesh used, different placement and anchorage of mesh, duration of follow-up, and use of validated questionnaires. With a total of 460 patients included in our study, this represents the largest report published to date examining the risk factors for vaginal erosions after the use of synthetic mesh to correct POP.

BMI has a well-known influence on tissue oxygenation and general wound healing (9), and obesity increases the risk of postoperative wound infections even when patients undergo massive weight loss after bariatric surgery (10,11). The effects of BMI on gynecological complications have been assessed in three studies (12–14): one failed to show a significant influence of obesity on perioperative complications (12), but the others found a significant higher incidence of operating times, intraoperative bladder injuries, vaginal infections, and hemorrhage for obese patients (13,14). The analysis of our patients confirms that in gynecological surgery, as in other types of surgery, obesity may determine complications particularly dependent on a good local microcirculation and oxygenation (9). The risk of erosions was 10 times greater in obese vs. non-obese patients and was the

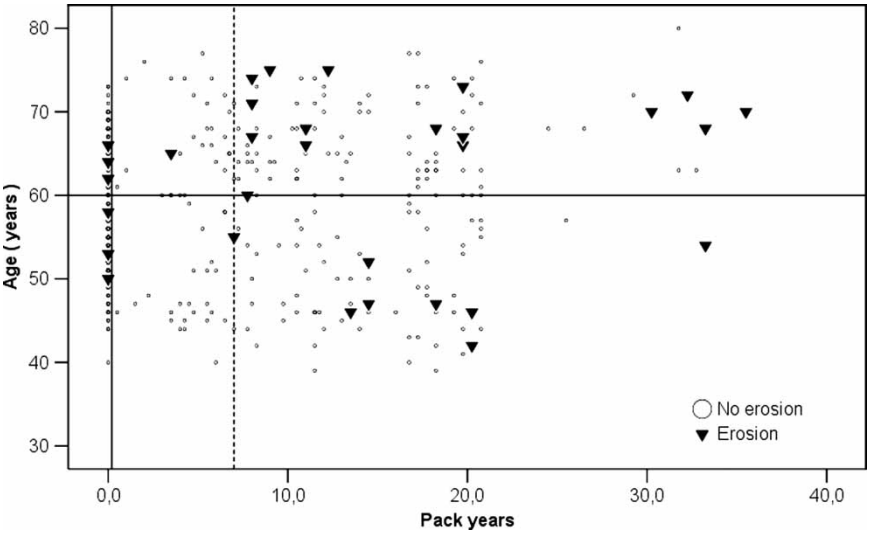

Figure 3. Scatter plot showing the age vs. pack years for the occurrence of vaginal erosions. Vertical continuous line: cut-off between smokers and non-smokers. Vertical dot line: cut-off between light and heavy smokers (seven pack years). Horizontal line: cut-off between adult patients (≥60 years) and young patients (<60 years).

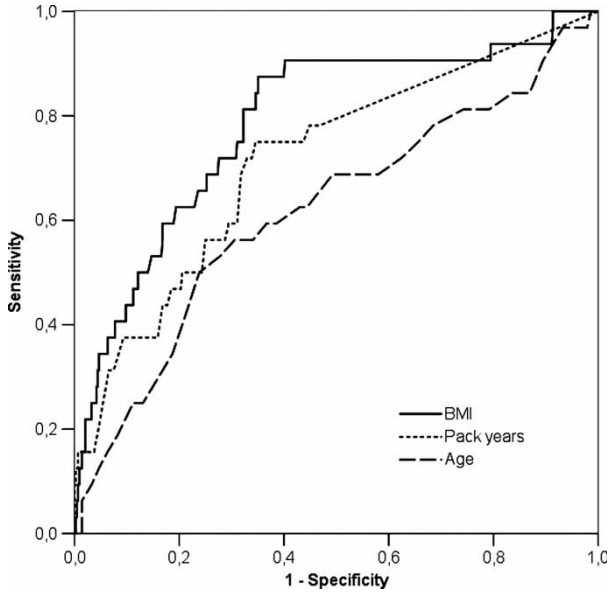

Figure 4. ROC curves of the three different variables (cut-offs: age = 60 years, BMI = 30, pack years = 7).

largest compared to that conferred by smoking or age. In this setting, obesity may be the most important determinant of erosions within this group of risk factors and its presence should alert the gynecologist to the likelihood of developing this complication.

Smoking is a common risk factor for a number of postoperative complications in almost all types of surgery (15–17). Components of tobacco influence wound healing (8) through dermal vessel vasoconstriction (18,19), the local formation of microthrombi (20,21), and a reduced local circulation (22,23). The smoking history is particularly important when local healing is dependent upon a good local vascularization (24–29). In gynecological surgery, a recent study attributed a three-fold increase in the chance to develop vaginal erosions to cigarette smoking (30). The number of cigarettes smoked in a patient's lifetime conferred a cumulative detrimental effect on wound healing, giving rise to a cut-off point in the number of cigarettes smoked for the increased risk of erosions (30). Here we found almost a four-fold increase in the risk of developing erosions in smokers. Furthermore, the risk of erosions in those with a pack year history less than seven years was approximately similar to non-smokers, suggesting that patients who smoke should be classified into the subgroups 'light or 'heavy' smokers. This would allow one to clearly identify the heavy smokers (more than seven pack years) as the only group carrying a significantly greater risk of developing vaginal erosions. Part of these results has also been confirmed by a second study in patients undergoing sacroabdominal colpopexy (31).

Finally, age has an important influence on the occurrence of vaginal erosions, probably by altering tissue vascularization and the healing ability of tissues (30). The detrimental role of the aging process on wound repair has been reported in lab-based studies and clinical trials for many years, forming a widely accepted body of evidence (30). The majority of more recent studies defined alterations in keratinocyte proliferation (32), the function of inflammatory cells (macrophage and T cell) (33,34), reduced extracellular matrix synthesis (34–36), impairment of angiogenesis (37,38). The results of this study demonstrate that age was a significant risk factor for the occurrence of vaginal erosions, since more than half occurred in patients more than 60 years of age. However, age conferred the lowest risk when compared to that of the other factors (BMI and smoking). Importantly, this tells us that a lifestyle free from obesity and smoking is more important than the ageing of tissues in relation to the risk of vaginal erosions after mesh repair of pelvic prolapse.

The implications of our findings are significant, as a simple set of question (age, height, and weight for BMI and number of pack years for smoking) gathered during the first visit before surgery may give the gynecologist a rough estimation of the risk of vaginal erosions. This should allow him to identify those patients that are at greater risk so that they can tailor specific preventative measures. However, we adopted strict inclusion criteria over five years of clinical activity, selecting a high number of treated patients, and the main limitation of our study lies in its retrospective nature. Specifically, when surgery was conducted, we did not adopt an objective methodology when measuring the quality and quantity of smoking (or of passive smoking), such as

Table IV. ROC curve analysis and results for the different variables including the sensibility and specificity obtained for the cut-offs selected.

	Variable	Area under the curve	95% Confidence Interval	*p*-Value	Cut-off	Sensibility	Specificity
BMI (kg/m^2)	0.787	0.700	0.874	<0.001	30	0.875	0.633
Pack years	0.715	0.617	0.813	<0.001	7	0.750	0.654
Age (years)	0.618	0.507	0.729	<0.001	60.5	0.594	0.614

analyzing the levels of specific metabolites in the urine or performing preoperative lung function studies. Furthermore, some data that could have influenced the occurrence of vaginal erosions, for example, the estrogen status or whether the patient was receiving hormone replacement therapy, were not documented in all medical notes. For this reason, prospective controlled trials are now necessary in order to evaluate and control the influence of such factors as well as to confirm our findings.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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