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Original Article

Risk factors for incisional hernia in gynecological cancer patients

Suat C Ulukent¹, Eser S Ozyurek², Inanc S Sarici¹, Osman S Gunkaya³, Semra Yuksel³, Aysu Akca³, Nuri A Sahbaz¹, Emel Canaz⁴, Ozgur Akbayir⁴

¹Department of General Surgery, Kanuni Sultan Suleyman Training and Research Hospital, Istanbul; ²Department of Obstetrics and Gynecology, Bagcilar Training and Research Hospital, Istanbul; Departments of ³Obstetrics and Gynecology, ⁴Gynecological Oncology, Kanuni Sultan Suleyman Training and Research Hospital, Istanbul

Received March 13, 2016; Accepted May 26, 2016; Epub August 15, 2016; Published August 30, 2016

Abstract: Purpose: The purpose of this study was to analyze retrospectively the risk factors for incisional hernia (IH) in a group of gynecological cancer patients operated with abdominal midline incisions. Methods: We retrieved retrospectively data of gynecological cancer patients with midline incisions from the clinical database of Kanuni Sultan Suleyman Training and Research Hospital Gynecological Oncology Department, within the time period 2001 to 2015. Patients with IH were analyzed for age, body mass index (BMI), smoking, and the presence of additional medical disorders, previous laparotomies, supraumbilical extension of incision, operative complications, postoperative hemoglobin levels, surgical site infections (SSI), adjuvant chemotherapy, abdominal radiotherapy and duration of follow-up. Results: 1369 gynecological cancer patients were operated with midline incisions. 80 patients had IH with a rate of 5.84% (95% CI: 4.56-7.04) incidence. With univariate analysis of demographic findings and risk factors; age, BMI, operative complications, postoperative hemoglobin levels, SSI, adjuvant chemotherapy and duration of follow-up were statistically significant. Multivariate analysis revealed; age [OR: 1.06 (95% CI: 1.02-1.09)], SSI [OR: 2.74 (95% CI: 1.08-7)], adjuvant chemotherapy [OR: 2.67 (95% CI: 1.2-5.9)] and duration of follow-up [OR: 1.03 (95% CI: 1.1-3.5)] as independent predictors of IH. Conclusion: In gynecological cancer patients operated with a midline incision, presence of independent risk factors (i.e.: the patient age, SSI, adjuvant chemotherapy) and prospects for survival may necessitate continued attentiveness to the persisting risk of IH formation in a longer term follow-up. In the presence of risk factors and an expectancy of a prolonged remission; it remains to be further proven in randomized controlled prospective studies, whether prophylactic mesh placement at the time of index procedure, may prevent this unpleasant morbidity.

Keywords: Midline incision, incisional hernia, risk factors, gynecological cancer

Introduction

Incisional hernia (IH) is one of the most common long term complications following laparotomies with midline incisions. The incidence of IH is reported to occur in 2 to 20% of these cases. It is commonly known to be due to improper closure or recovery of the fascia. Pain as well as incarceration (15%) and strangulation (2%) may cause considerable morbidity as a consequence of IH [1]. Management of gynecological cancers in modern practice, supplemented with chemotherapeutic agents, better targeted radiotherapies, postoperative care have achieved improved survival rates and times [2, 3]. During and following recovery, it is still not well defined if, for how long and for

whom: the chance and alertness for IH should persist and if possible precautions taken. We analyzed our clinical data comprised of ovarian, endometrial and cervical cancers operated with abdominal midline incisions. Our IH group study is to our knowledge one of the longest surveillances reported. We investigated the risk factors for IH following a laparotomy with a midline incision for gynecological cancers patients.

Material and methods

Study design

In a case-control retrospective analysis of 80 women diagnosed with an IH from a group of 1369 female operated for ovarian (n=773),

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Table 1. Distribution of cases in different disease categories in the study and the control groups

	Incisional Hernia n (%)	Control group n (%)	Total n (%)
Ovarian Cancer	27 (17.6)	126 (82.4)	153 (100.0)
Endometrial Cancer	38 (19.3)	159 (80.7)	197 (100.0)
Cervical Cancer	15 (20.3)	59 (79.7)	74 (100.0)
Total	80 (19.0)	344 (81.0)	424 (100.0)

Table 2. Cumulative percentages of incisional hernias

Months	Annual Incidence	Cumulative Number (%)
3-12	45	45 (56.3)
12-24	24	69 (86.3)
24-36	2	71 (88.8)
36-48	2	73 (91.3)
48-60	2	75 (93.8)
60-72	2	77 (96.3)
72-84	1	78 (97.5)
84-96	1	79 (98.8)
96-113	1	80 (100)

endometrial (n=441) or cervical cancers (n=155) within the time period 2001-2015, at Kanuni Sultan Suleyman Training and Research Hospital Gynecological Oncology Department, were analyzed to define risk factors for IH. Sample size calculation for a control group assignment was performed to be able to detect a 50% variation in the rate of at least 2-3 risk factors; regarding an α -error of 0.05 and a power of 80%. 344 control patients who were operated with a midline incision and had not by the time of the study been diagnosed with an IH were enrolled as the control group. The control group was comprised of 126 ovarian cancers; 159 endometrial cancers; and 59 cervical cancers by systematic randomization by which: each of the (4 control cases per 1 study case) matched control case group was randomly picked from the gynecological oncology database by using a random number generator, matching each hernia case with 4 control cases, with the same exclusion criteria and with the same oncological diagnosis as the study case; totaling up to 344 patients (**Table 1**). This study had a sufficient statistical power to detect a 50% decrease in the rate of the presence at least 2 risk factors in the control group in contrast to the study group.

Patient management

Preoperative and postoperative management of all these patients were done with the same protocol by 3 certified gynecological oncologists in a 14 years' time period. Preoperative antibiotic and deep venous thrombosis prophylaxis were performed routinely. Hemoglobin levels were corrected to 10 g/dL with blood transfusions, when necessary. General conditions of patients with medical co-morbidities including diabetes mellitus (DM), hypertension, hypo/hyperthyroidism were optimized (regulation of blood glucose levels, blood pressures, ensuring an euthyroid status). Patients were operated with midline incision. Bladder, ureter, big vessel injuries, excessive bleeding episodes were noted as operative complications. Facial closure was performed continuously with small stitches placed 5-6 mm from the wound edge, only through the aponeurosis excluding the rectus muscle, by using polydioxanone loop suture number 1 (PDS® II, Ethicon, Illinois, USA), continuously. After the facial closure, subcutaneous space liberally was irrigated with saline. Surgical site infection (SSI) were considered when there was foul and/or excessive colored discharge from the incision line with any wound dehiscence, and the condition was confirmed by microbiological culture or plasma markers of infection within the first month following surgery. Skin sutures were not taken by the postoperative 12 days. Patients wore abdominal corsets for 3 months following the operations, routinely. If necessary, adjuvant chemotherapy was administrated after the postoperative 3 weeks.

Follow-up

Patients were routinely examined for cancer recurrence every 3 months within the first 2 years; and every 4 months for 3 additional years; and then, annually. In each visit, a physical examination of the pelvis and the incisions were performed. All data were recorded in digital files at our polyclinic. In conditions where necessary, a magnetic resonance imaging or a computerized tomography (CT) was performed. If there was any suspicion for IH which was defined as any fascial gap or protrusion detected by physical examination or fascial gap/separation in axial images on CT or ultrasonography, these cases were referred to our general surgery department. The decision to repair or

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Table 3. Univariate analysis of patient characteristics

	Control group	Incisional Hernia	P value
Preoperative factors			
Age mean, (\pm SEM ^a)	52.2 (\pm 0.6)	57 (\pm 1.5)	0.001
Body Mass Index mean, (\pm SEM)	28.5 (\pm 0.33)	31.2 (\pm 0.58)	0.02
Smoking, n (%)	77 (25.4)	15 (19)	0.74
Hypertension, n (%)	79 (23)	13 (16.3)	0,24
Diabetes Mellitus, n (%)	52 (15.1)	14 (17.5)	0.61
Chronic obstructive pulmonary disease, n (%)	7 (2)	1 (1.3)	0.68
Hypothyroidism, n (%)	14 (4.1)	5 (6.3)	0.38
Previous laparotomies, n (%)	114 (33.1)	23 (29.1)	0.49
Operative Factors			
Operative complications* n (%)	2 (2.5)	27 (7.8)	0.09
Supraumbilical extension of incision, n (%)	249 (72.4)	60 (75)	0,64
Postoperative Factors			
Postoperative Hemoglobin level (g/dL) mean (\pm SEM)	10.9 (\pm 0.09)	10.1 (\pm 0.18)	0.04
Surgical site infection, n (%)	33 (9.6)	17 (21.3)	0.009
Adjuvant Chemotherapy, n (%)	52 (15.1)	20 (25)	0.03
Abdominal Radiotherapy, n (%)	50 (14.5)	12 (15)	0.91
Duration of follow-up, month	27.9 (\pm 1.9)	53.4 (\pm 3.9)	<0.001

*Operative complications: Big vessel and Urinary tract injury. ^aStandard error of the mean.

Table 4. Logistic regression analysis of significant parameters

	Odds Ratio (95% CI)	p-value
Age	1.06 [1.02-1.09]	<0.001
Body Mass Index	1.04 [0.98-1.1]	0.21
Postoperative hemoglobin levels	1.06 [0.84-1.3]	0.62
Surgical Site Infections	2.74 [1.08-7]	0.03
Adjuvant chemotherapy	2.67 [1.2-5.9]	0.01
Duration of follow-up	1.03 [1.1-3.5]	<0.001

expectantly manage was made by taking into consideration the clinical urgency (strangulation, incarceration, etc.), the hernia size, and the life expectancy, medical condition of the patient, age, the time passed since the operation and if a secondary surgical intervention was being planned for the primary pathology. If necessary, the repair was performed by using polypropylene or dual mesh in each individual case.

Statistical analyses

Potential risk factors extracted from the database were *preoperative factors* including age, BMI, smoking, the presence of additional medical disorders DM, hypertension, chronic ob-

structive pulmonary disease (COPD), hypothyroidism), previous laparotomies; *operative factors* including operative complications (big vessel and urinary tract injury), supraumbilical extension of incision; and *postoperative factors* including SSI, postoperative hemoglobin levels, adjuvant chemotherapy, abdominal radiotherapy and duration of follow up. Exclusion criteria in the study included having had neoadjuvant chemoradiotherapy, presence of treated or untreated previous IH, patients who had to be reoperated via the same

abdominal incision during the follow-up period for any other indications, patients with postoperative follow-up durations shorter than 6 months, patients with fascial dehiscence with secondary healing, being rendered as unresectable during the operation; pelvic exenteration; when cancer surgery included bowel resection/colostomy/ileostomy/iatrogenic bowel injury and missing clinical-laboratory data.

Univariate comparison of the hernia and the control groups were carried out. The potential risk factors as stated above were compared among the study and the control groups, summarized in (Table 3). The categorical data were analyzed with Chi-square and Fisher's exact tests where necessary. Numerical univariate

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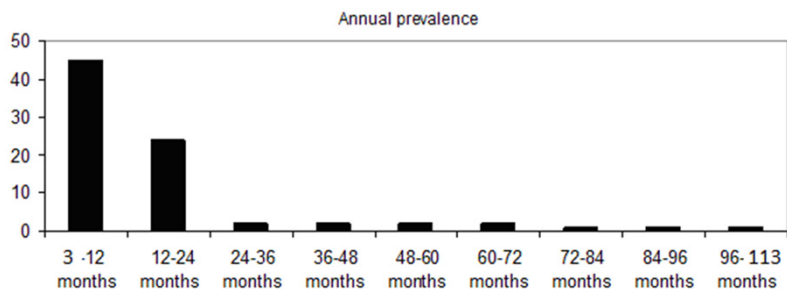


Figure 1. Number of cases of incisional hernias within 12 months segments following the operation.

comparisons were made with Student's-t test. Significance of α -errors were considered where $P < 0.05$. Parameters with p values lower than 0.05 were then included in the logistical regression analysis with 'hernia formation' as the independent variable (**Table 4**). Data analysis was performed using Microsoft Excel 2013, and SPSS 17.0 for Windows (SPSS Inc., Chicago, IL).

Results

From 1369 gynecological cancer patients operated with midline incision, 80 patients with a 5.84% rate of incidence (95% CI: 4.56-7.04%) were diagnosed with clinical and radiological findings of IH within a time period of 3 to 113 months postoperatively (mean or median 19 ± 2.3 months). The distribution of cases in different disease categories comprising the study and the control groups was as in **Table 1**. The incidence of IH cases are summarized in **Figure 1** and **Table 2** as a function of time. Eighteen (22.5%) of the IH cases were operated (17 planned cases and 1 emergency intervention due to bowel strangulation), and the rest were non-surgically managed. One (5.6%) patient re-operated due to the recurrence of the hernia.

The mean age of the IH group was 57. Mean BMI of the IH group was 31.2. Fifteen patient (19%) were smokers. Thirteen patients (16.3%) had hypertension, 14 patients (17.5%) had DM, 5 patients (6.3%) had hypothyroidism and 1 patient (1.3%) had COPD. Totally, 33 patients (41.4%) in the hernia group had co-morbidity. Twenty three (29.1%) patient had previous laparotomies. Sixty patient (75%) of the IH group had a supraumbilical extension of incision and 27 patients (7.8%) had operative complication, the mean postoperative hemoglobin level was 10.1 g/dL, SSI developed in 17 patients (21.3%)

and 20 patients (25%) received adjuvant chemotherapy, 12 patients (15%) had abdominal radiotherapy. Finally the mean duration of follow up was 53.4 ± 3.9 (Min-max: [5-129] months) (**Table 3**).

The mean age of the control group was 52.2. Mean BMI of the control group was 28.5. Seventy-seven patients

(25.4%) of control group were smokers. Seventy nine patients (23%) had hypertension, 52 patient (15.1%) had DM, 7 patients (2%) had COPD and 14 patients (4.1%) had hypothyroidism. Totally, 152 patients (44.2%) had co-morbidity in control group. One hundred fourteen patients (33.1%) had previous laparotomies. Two hundred forty nine patients (72.4%) of the control patients had supraumbilical extension of incisions Two patients (2.5%) had operative complication, the mean postoperative hemoglobin level was 10.9 g/dL and 33 patients (9.6%) had SSI, 52 patients (15.1%) had adjuvant chemotherapy and 50 patients (14.5%) had abdominal radiotherapy. Finally the mean duration of follow up was 27.9 ± 1.9 (Min-max: [3-139] months) (**Table 3**).

Univariant analysis performed to compare the rate of the presence of risk factors and was considered significant when p values of 0.05 or less. Age, BMI, operative complications, post-operative hemoglobin levels, SSI, adjuvant chemotherapy and duration of follow up were statistically significant between the two groups in univariant analyses (**Table 3**). These variables were then analyzed with logistic regression analysis. The logistic regression model was found significant ($P < 0.001$) with Nagelkerke R Square value of (0, 27) and the model being able to represent the observations at a rate of (96.4%). Of the variables included in the analysis age, SSI, adjuvant chemotherapy, duration of follow up were found to be independent determining factors for the appearance of IH (**Table 4**).

Discussion

Incisional hernia is serious socioeconomic and medical problem. About 4.3% of IHs are oper-

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ated for incarcerations as well as strangulations; and 20-60% rates of recurrence are observed following repair [4, 5]. On the other hand, about 60% of IH may even be latent [6].

IH can occur after any type of abdominal incision, but are frequently observed in longitudinal incisions (10.5%) and transverse incisions (7.5%) [7]. In the current study, IH incidence was 5.84% (95% CI: 4.56-7.04%) and this rate is lower than prevalence reported in the literature [8]. The main causes for the lower rates of IH in our patients compared to previously reported rates might be; the implementation of fundamental rules of safety, associated with incision closure were adhered to. In a large randomized control trial, small stitches placed 4-6 mm from wound edge in the aponeurotic layer, reduced the risk of IH from 18% to 5.6% [9]. The elective nature of the operations, the characteristics of our study population (all cases being female, exclusion of iatrogenic bowel injury/resection, clean/clean-contaminated surgical procedures), the same 3 certified gynecological oncologist conducting the primary operations, postoperative wound care (corset use in the postoperative 3 months) and may be some of the other causes for the lower rates of IH in our patients [10].

Abdominal fascia reaches 70-80% of former tension strength at 120 days and 73-93% at 140 days after operation [11]. Until recently, IH was assumed to result mostly from a technical failure in surgical closure of incision [12]. Currently it is has been established that patients related factors, surgical and postoperative factors which all affect normal wound healing, also influence their development. Yet, predisposition to IH is in fact detectable very early in the postoperative period as various degrees of separation of the rectus muscles, but other factors probably determine if and when they become clinically detectable [13]. According to the current study, after analyzing the potential risk factors, independent positive predictors for IH were *age*, *SSI*, *adjuvant chemotherapy* and *duration of follow up*.

Patient age was a significant determining factor for IH. In current study, there was statistically significant difference in mean age between the hernia (mean age; 57) and the control (mean age; 52.2) groups ($P=0.001$). This is most probably due to worsening of connective tissue

repair, hematological angiogenetic defects, accompanying diseases or neurological problems of older patients [14, 15].

Surgical site infection (SSI) is frequently documented as the most important independent risk factor for development of IH and is considered to double the risk [16]. In current study, SSI was one of the independent factors with an OR: 2.74 (95% CI: 1.08-7). SSI still stands out as significant predictors of IH despite having excluded cases with bowel resections and injuries which would have reclassified the wounds as contaminated.

In current study adjuvant chemotherapy is one of the independent variable with an OR: 2.67 (95% CI: 1.2-5.9). Adjuvant chemotherapy is a significant determining factor in the early period of wound healing, probably due to immune suppression, malnutrition or deranged tissue renewal, however, it still is an intriguing finding. It is recommended that adjuvant chemotherapy should be given 2-3 weeks after completion of acute wound healing [17]. The unique factor about this study is that the cases studied were gynecological cancers with a high percentage receiving adjuvant chemotherapy.

Duration of follow up were found as significant determinants of IH in the multivariate analysis of our data (OR: 1.03; 95% CI: 1.1-3.5). Follow-up durations in essence define the time interval during which the patient maintains contact with health facilities including physical examinations being performed, laboratory and radiological surveys to detect recurrent disease and other consequences of oncological treatment. Patients may drop off from follow-up for various reasons including change of locations, change of medical facility to continue their treatments, neglect as well as mortality. Hence, drawing conclusions from this finding is open to bias in a retrospective analysis; however, it still is an intriguing finding.

Most of the IH is observed within the 2 years following operation; however, they are reported to be observed as late as 10 years in case presentations [18, 19]. Management of gynecological cancers in modern practice, supplemented with chemotherapeutical agents, better targeted radiotherapies and postoperative care have achieved improved survival rate, one of the expenses of which may be encountering

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even higher rates of IH. The current study has shown that most of the IH (56%) following midline incisions to treat gynecological cancers occur within the first postoperative year; (86.3%) by the end of the second year; and (100%) within as late as 113 months (**Figure 1; Table 2**). Our rates are in complete accordance with findings from 2 studies by Höer et al. and Mudge & Hughes et al. [20, 21]. These two studies have identically reported in long surveillance series that as high as 10-11% of IHs are detected after 5 years.

None of the tested risk factors including; BMI, smoking, DM, hypertension, COPD or hypothyroidism, previous laparotomies, supraumbilical extension of incision, operative complications, postoperative hemoglobin level and abdominal radiotherapy, was found to be a significant predictor of IH in our study group. The cause of this contrast may at least be having received chemo-radiotherapy, as Spencer et al. have suggested, underestimating the essential role of other potential risk factors [22].

BMI was not found to be significant factor ($P=0.21$) which is contrary to the classical view, but in agreement with findings of Rettenmaier et al. and Spencer et al. who reported the insignificance of BMI and suggesting that an increasing BMI may not be a predisposing factor, which is the case in our study, as well [17, 22].

Smoking is one of the well-known independent risk factors for IH in literature [22], but in our study, it was not found to be a significant factor ($P=0.74$) which might be due to unrevealed or inaccurate personal data (regarding the amount, current status, or history of smoking).

Local factors are more important than systemic factors in wound healing or dehiscence [23]. Although DM is accepted as one of the risk factors in IH development, well-regulated DM is not [15]. This must be why we did not observe a significant association with mostly well-regulated DM in our study.

Despite being reported as early risk factors [24, 25], COPD and previous laparotomies did not reach statistical significance in our study ($P=0.68$ and $P=0.49$ respectively). Nevertheless, routine early postoperative corset use in cancer patients operated with a midline incision may be negating the effects of COPD and previous laparotomy incisions in our study. Despite the lack of any reference to the efficacy

of this precaution in current literature, we consider it to be one of the contributing factors to the low rates of IH in our cases. This argument remains to be proven in further randomized controlled prospective studies [7].

In literature, the reported hemoglobin levels positively associated with IH are measured in the preoperative period [20]. In our study, the postoperative first day hemoglobin levels, representing the healing period did not pose any significant difference ($P=0.62$).

In different clinical groups of patients who have gone through open abdominal surgery, promising results have been reported for prophylactic mesh placement [26]. The role of predefining gynecological cancer patients bearing proven risk factors for IH and application of prophylactic mesh or retention sutures in these cases is not yet well defined in well-designed studies. In a retrospective analysis of patients who underwent applications of retention sutures for gastrointestinal tract malignancies; no significant difference was detected in terms of IH, but evisceration and SSI were significantly lower in retention sutures group [27, 28]. Performing of laparoscopic surgery for cancer patient's treatment is also an alternative way for prevention of IH in high risk patients.

This study has some limitations to be noted. Because of its retrospective design, it may be vulnerable to selection bias. In order to eliminate the effect of selection bias, the formation of the control group was systematically randomized by matching each hernia case with 4 control cases with characteristics explained in the materials and method section and with the same oncological diagnosis. Despite studying gynecological cancers being operated, number of consequential events was statistically insufficient to make subgroup analysis for tumor types, whether the primary resection was optimal. We do not have any data to represent the patients' nutritional status or changes in BMI during treatment.

Conclusion

Gynecological cancer patients operated with a midline incision, presence of independent risk factors (i.e.: age, SSI, adjuvant chemotherapy) and prospects for survival may necessitate continued attentiveness to the persisting risk of IH formation in a longer term follow-up.

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Predefining risk factors may be important in the prevention of IH. In the presence of risk factors including age, adjuvant chemotherapy, SSI, and an expectancy of a prolonged duration of follow-up duration, probably reflective of a long remission period in gynecological oncology cases; it remains to be further proven in randomized controlled prospective studies, whether prophylactic mesh placement at the time of index procedure, may prevent this unpleasant morbidity.

Disclosure of conflict of interest

None.

Address correspondence to: Inanc S Sarici, Departments of General Surgery, Kanuni Sultan Suleyman Training and Research Hospital, 4. Bölge Atakent Mahallesi Toki Menekse Evleri C2-7 Daire: 49 Halkalı-İstanbul. Tel: +905532271140; E-mail: issarici2015@gmail.com

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