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Impact of age on groin hernia profiles observed during laparoscopic transabdominal preperitoneal hernia repair

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Abstract

Background How increasing age affects the characteristics of groin hernia remains uncertain. This study evaluated the association between age and the type of groin hernia, especially with respect to its multiplicity, observed during laparoscopic transabdominal preperitoneal (TAPP) hernia repair.

Methods We retrospectively evaluated 634 consecutive patients with primary gr**o**in hernia who underwent laparoscopic TAPP repair between October 2000 and June 2017. Patients were stratified into 4 age groups: < 60 years, 60–69 years, 70–79 years, and 80 years or older.

Results The incidence of occult contralateral hernia and multiple ipsilateral hernias increased significantly with each increasing age group: 7.3%, 10.4%, 12.7%, and 20.8% for occult contralateral hernia ($p = 0.005$), and 5.6%, 9.2%, 16.8%, and 21.7% for multiple ipsilateral hernias ($p < 0.001$), respectively. Univariate analyses showed that an older age (age ≥ 70 years) was the only factor significantly associated with the presence of multiple groin hernias (odds ratio, 2.69; 95% confidence interval, 1.89–3.81; $p < 0.001$). In patients with multiple ipsilateral hernias, the prevalent form in men was a pantaloons hernia, with an incidence of about 70% across all age groups, whereas in women it was groin hernias, with one component being a femoral hernia, an obturator hernia, or both.

Conclusions The multiple occurrence of groin hernias, either unilaterally or bilaterally, was a clinical feature in the elderly.

Keywords Groin hernia · Laparoscopic · TAPP · Age · Occult contralateral hernia · Multiple ipsilateral hernia

The incidence of groin hernia increases with age, especially in men, through the fifth to seventh decades of life [1–3], presumably because of the loss of tissue strength [4, 5] or the long-term effect of increased intra-abdominal pressure [6, 7]. Indeed, the cumulative incidence of groin hernia in men steadily increases with increasing age: 7.3% at age 24–39 years, 14.8% at age 40–59 years, and 22.8% at age 60–74 years [1]. Similarly, an older age is associated with a greater incidence of groin hernia among women [1]. Since the elderly population is continuing to expand in many countries worldwide [8], the number of surgical candidates with groin hernia is likely to increase for the foreseeable future. Hence, an understanding of the clinical profiles of groin hernia in the elderly might be beneficial.

Considering the above-mentioned factors associated with the genesis of groin hernia, the number of patients with more than one hernia can be expected to increase with age. The incidences of multiple groin hernias, such as bilateral hernias [9–19] and multiple ipsilateral hernias [20, 21], have been previously reported. However, these incidences were for the entire cohorts; hence, the actual impact of age on the characteristics of groin hernia has not been well defined.

The aim of this study was to evaluate the association between age and (1) the type of hernia and (2) multiplicity of hernias observed in patients undergoing laparoscopic transabdominal preperitoneal (TAPP) repair, which provides an opportunity for a bilateral evaluation of the groin anatomy from inside the peritoneal cavity.

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Materials and methods

Study design and participants

A total of 822 patients with groin hernia underwent laparoscopic TAPP hernia repair at the Department of Surgery, Showa-Inan General Hospital between October 2000 and March 2006, the Department of Surgery, Okaya Municipal Hospital between April 2010 and June 2017, or the First Department of Surgery, Shinshu University School of Medicine between April 2007 and June 2017. Among these, 634 patients with primary groin hernia were finally enrolled in the present study, and 188 patients were excluded for the following reasons: medical records were not available for 130 patients, and 58 patients were diagnosed as having recurrent groin hernia. Patients were stratified into the following four groups according to their age: < 60 years ($n = 178$), 60–69 years ($n = 163$), 70–79 years ($n = 173$), and ≥ 80 years ($n = 120$). The data for these patients were then analyzed retrospectively.

We consider laparoscopic TAPP repair to be the procedure of choice for groin hernia, even in emergency situations, unless the patient is unfit for general anesthesia or has undergone previous extensive pelvic surgery. All the repairs were performed or supervised by two experienced surgeons (TY and SM) who were fully qualified under the endoscopic surgical skill qualification system in Japan. Using a standard three-port technique, a peritoneal incision was made at a point on the internal ring. After completing the dissection of the preperitoneal space, we applied a polypropylene mesh to cover the whole myopectineal orifice. The mesh was fixed with staples to the Cooper's ligament and the rectus sheath medially and to the anterior abdominal wall laterally. The peritoneal incision was then closed with a running suture. During laparoscopic TAPP repair, the contralateral side was systematically inspected intra-abdominally and hernia repair was performed simultaneously if occult contralateral hernias were observed. Prior informed consent was obtained from all the patients who received an operation.

Definition

The preoperative diagnosis was based on clinical findings, and, if necessary, ultrasonography and computed tomography imaging. Occult hernia was defined as intraoperative laparoscopic findings of a significant peritoneal protrusion at the site of the hernia orifice that had not been diagnosed preoperatively, based on past literature [9]. Multiple groin hernias were defined as more than one hernia located either bilaterally, ipsilaterally, or both.

Factors analyzed

According to the statement of risk factors for the development of groin hernias in adults [22], the following host factors were analyzed to identify risk factors for (1) multiple groin hernias and (2) the presence of femoral hernia or obturator hernia using univariate and multivariate analyses: age (below versus above the cutoff value established using a receiver operating characteristic [ROC] curve analysis), gender (female versus male), pulmonary disease (present versus absent), diabetes mellitus (present versus absent), smoking habit (yes versus no), previous prostatectomy (yes versus no), and body mass index (22 or more versus < 22, with the cutoff corresponding to the median value).

Statistical analysis

Continuous data are expressed in median values (range), unless stated otherwise. Data were compared among 4 groups using the Kruskal–Wallis test for continuous variables or the χ^2 test for categorical ones. The association between age and the incidence of multiple groin hernias was evaluated using the Cochran–Armitage test for trends. The optimal cutoff value for age predicting the presence of multiple groin hernias was selected so as to maximize the Youden index. Multivariate logistic regression analyses were performed by the forward selection of covariates that were identified as being significant using a univariate analysis with a cutoff p value of 0.20, after the elimination of possible confounders. Values of $p < 0.05$ were considered statistically significant. Data were analyzed using JMP version 12 (SAS Institute Inc., Cary, North Carolina, USA) statistical software package.

Results

Patient characteristics and operative outcomes

There were 520 men and 114 women with a median age of 68 years (range 19–98 years). A total of 823 groin hernias were observed in these 634 patients. The patient demographics for the 4 age groups are shown in Table 1. The proportion of patients with comorbidities was significantly associated with an increasing age except for that of patients with diabetes mellitus and a history of a smoking habit. Interestingly, patients aged 80 years or older were more likely to be female ($p < 0.001$) and to have a lower body mass index ($p = 0.009$) than other age groups. Although the morbidity rate increased significantly with advancing age, no such association was seen in the number of postoperative recurrences. Postoperative recurrence was observed in two male patients aged

Table 1 Clinical features of patients stratified according to age group

	< 60 years (*n* = 178)	60–69 years (*n* = 163)	70–79 years (*n* = 173)	≤ 80 years (*n* = 120)	*p* value
Demographic characteristics					
Gender (female/male)	38/140	16 /147	27/146	33/87	< 0.001
Comorbidity					
Cardiovascular disease	6 (3.4)	15 (9.2)	39 (22.5)	28 (23.3)	< 0.001
Pulmonary disease	7 (3.9)	14 (8.6)	13 (7.5)	17 (14.2)	0.016
Diabetes mellitus	9 (5.1)	21 (12.9)	17 (9.8)	8 (6.7)	0.058
Cerebrovascular disease	4 (2.2)	17 (10.4)	23 (13.3)	17 (14.2)	< 0.001
Smoking habit	100 (56.2)	91 (55.8)	80 (46.2)	52 (43.3)	0.050
History of prostatectomy	0 (0.0)	13 (8.0)	13 (7.5)	4 (3.3)	0.001
Body mass index[a]	22.0 (13.7–30.9)	22.8 (14.5–35.8)	22.5 (16.3–29.2)	21.8 (13.8–27.6)	0.009
Intraoperative data					
Operation time (min)[a]	78 (46–284)	85 (32–210)	88 (50–243)	93 (42–299)	0.001
Postoperative course					
Patients with complications	23 (12.9)	33 (20.2)	45 (26.0)	29 (24.2)	0.015
No. of complications					
Seroma	17 (9.6)	29 (17.8)	33 (19.1)	26 (21.7)	0.023
Hematoma	1 (0.6)	1 (0.6)	6 (3.5)	2 (1.7)	0.105
Surgical site infection	4 (2.2)	2 (1.2)	2 (1.2)	0 (0.0)	0.401
Chronic pain[b]	1 (0.6)	0 (0.0)	1 (0.6)	1 (0.8)	0.759
Postoperative recurrence[c]	0 (0.0)	1 (0.6)	1 (0.6)	0 (0.0)	0.619

Values in parenthesis are percentage unless otherwise indicated

[a]Values are median (range)

[b]Pain lasting for more than 6 months after surgery

[c]Median follow-up period of 56 months (range 4–139 months)

68 and 70 years, respectively. The recurrent hernia repairs were performed 4 and 6 months after the initial surgery, respectively. In both cases, the mesh had dislocated laterally.

Distribution of age and multiple groin hernias

The distribution for age and multiple groin hernias is shown in Table 2. Multiple groin hernias were seen in 190 cases (30.0%), the incidence of which increased significantly with age: 15.2% for patients less than 60 years, 26.4% for those with 60–69 years, 38.7% for those with 70–79 years, and 44.2% for those 80 years or older ($p < 0.001$). Similarly, the incidences of occult contralateral hernia, observed in 77 patients (12.1%) in total, and multiple ipsilateral hernias, observed in 80 patients (12.6%) in total, were also significantly associated with increasing age. Since all the estimated cutoff values for age predicting the presence of multiple groin hernias were around 70 years, we selected this value as the cutoff point for subsequent analyses (Table 3).

Predisposing factors for multiple groin hernias

Univariate analyses showed that a patient age of 70 years or older was the only factor significantly associated with the presence of multiple groin hernias, with an odds ratio of 2.69 relative to younger counterparts (Table 4). Similarly, the age group of 70 years or older was the only factor associated

Table 2 Incidence of multiple groin hernias stratified according to age group

	Total (*n* = 634)	< 60 years (*n* = 178)	60–69 year (*n* = 163)	70–79 year (*n* = 173)	≤ 80 year (*n* = 120)	*p* value
Multiple groin hernias	190 (30.0)	27 (15.2)	43 (26.4)	67 (38.7)	53 (44.2)	< 0.001
Bilateral hernias	149 (23.5)	19 (10.7)	34 (20.9)	54 (31.2)	42 (35.0)	< 0.001
Occult contralateral hernia	77 (12.1)	13 (7.3)	17 (10.4)	22 (12.7)	25 (20.8)	0.005
Multiple ipsilateral hernias	80 (12.6)	10 (5.6)	15 (9.2)	29 (16.8)	26 (21.7)	< 0.001

All values reported as *n* (%). Statistically significant was defined as a $p < 0.05$

Table 3 Cutoff value for age predicting the presence of multiple groin hernias

	Estimated cutoff value	AUROC	95% CI	Sensitivity (%)	Specificity (%)
Multiple groin hernias	68	0.644	0.597–0.688	69.0	55.4
Bilateral hernias	70	0.640	0.589–0.687	64.7	59.5
Occult contralateral hernia	71	0.598	0.527–0.665	59.7	58.7
Multiple ipsilateral hernias	70	0.663	0.601–0.719	68.8	57.0

AUROC area under the receiver operating characteristic curve, *CI* confidence interval

with the incidence of occult contralateral hernia and was an independent predictor of multiple ipsilateral hernias.

Cumulative incidence of groin hernia stratified according to age

Figure 1 shows the cumulative incidence of groin hernia stratified according to age. Every single groin hernia was counted as one. As age increased, the incidence of indirect hernia decreased, whereas that of femoral hernia increased. The incidence of femoral hernia or obturator hernia reached a peak at 80 years or older among all the enrolled patients, and this trend was likely a reflection of that seen in female patients. An ROC analysis showed that the cutoff point for age predicting the presence of a femoral or obturator hernia was 79 years, which yielded a sensitivity of 49.1% and a specificity of 80.1% with an area under the ROC curve of 0.670 (95% confidence interval 0.587–0.744). A multivariate analysis identified that a female gender, an age ≥ 80 years, and a lean body mass were independent predictors of the presence of femoral hernia or obturator hernia (Table 5).

Cumulative incidence and types of multiple ipsilateral hernias stratified according to age

Figure 2 shows the cumulative incidence and types of multiple ipsilateral hernias stratified according to age. Every single groin hernia was counted as one. The prevalent form was pantaloons hernia in men, with an incidence of about 70% across all age groups, whereas in women it was groin hernias in which one component was a femoral hernia, an obturator hernia, or both.

Discussion

Statement of principal findings

Although groin hernia is known to be more common in older adults [1–3], the impact of age on the characteristics of groin hernia has not been fully elucidated so far. One of the most important aspects of the present study was that the incidence of multiple groin hernias increased significantly with age, from 15.2% for patients less than 60 years of age to 44.2% for patients who were 80 years or older. In addition, an advanced age (age ≥ 70 years) was the only factor associated with the presence of multiple groin hernias when examined using a univariate analysis.

Interpretation with reference to other studies

We defined occult hernia as intraoperative laparoscopic findings showing an incidental defect at the site of the hernial orifice without an extra peritoneal incision, identical to the definition of Thumbe et al. [23]. Occult contralateral hernia was observed in 77 patients, corresponding to 12.1% of the all the enrolled patients and 13.7% of the patients who were diagnosed as having a unilateral groin hernia. These figures are in agreement with those reported in previous studies [9–19], resulting in an overall incidence of 7.3–25.3% and an incidence of 11.0–43.1% among those diagnosed as having a unilateral groin hernia (Table 6). Importantly, the incidence of occult contralateral hernia increased significantly with each increasing age group, reaching 20.8% among patients who were 80 years or older.

Whether incidentally discovered and asymptomatic contralateral defects should be simultaneously repaired during TAPP remains a matter of debate. So far, two studies have revealed a risk of developing a contralateral hernia from an asymptomatic defect identified during primary TAPP repair. One study revealed that 21% of patients in whom a contralateral incipient defect was identified during primary TAPP contralateral exploration subsequently developed a symptomatic hernia during a mean follow-up period of 112 months (range 16–218 months) [18]. Another study reported that 29% of patients with a contralateral incidental hernia defect developed a symptomatic hernia within a 12-month median follow-up period [23]. Accordingly, some contralateral asymptomatic defects can eventually develop into symptomatic hernias, but which types of defects should be repaired remains uncertain. Hence, as stated in the latest international guidelines for groin hernia management [22], the establishment of a universal definition of 'occult hernia' and a long-term follow-up trial may lead to the identification of patients with a high risk of early contralateral hernia development.

Table 4 Univariate and multivariate analysis to identify risk factors for multiple groin hernias

Variables	No. of patients	Multiple groin hernias ($n=190$)			Occult contralateral hernia ($n=77$)				Multiple ipsilateral hernias ($n=80$)			
					Univariate analysis			Multivariate analysis	Univariate analysis			Multivariate analysis
		n	OR (95% CI)	*p* value	n	OR (95% CI)	*p* value	OR (95% CI) *p* value	n	OR (95% CI)	*p* value	OR (95% CI) *p* value
Age (years)												
< 70	341	70	Ref		30	Ref		Ref	25	Ref		Ref
≤ 70	293	120	2.69 (1.89–3.81)	< 0.001	47	1.98 (1.22–3.23)	0.006	1.94 (1.19–3.17) 0.008	55	2.92 (1.77–4.82)	< 0.001	2.88 (1.74–4.78) < 0.001
Gender												
Male	520	151	Ref		58	Ref		Ref	59	Ref		Ref
Female	114	39	1.27 (0.82–1.95)	0.280	19	1.59 (0.89–2.75)	0.116	1.52 (0.86–2.68) 0.147	21	1.76 (1.00–3.00)	0.048	1.64 (0.92–2.94) 0.097
Pulmonary disease												
No	583	176	Ref		73	Ref			73	Ref		
Yes	51	14	0.88 (0.45–1.62)	0.680	4	0.59 (0.18–1.52)	0.301		7	0.90 (0.41–2.25)	0.806	
Diabetes mellitus												
No	579	170	Ref		68	Ref			69	Ref		Ref
Yes	55	20	1.37 (0.76–2.43)	0.287	9	1.47 (0.65–3.01)	0.336		11	1.85 (0.87–3.63)	0.105	2.15 (1.03–4.51) 0.042
Smoking habit												
No	311	94	Ref		36	Ref			40	Ref		
Yes	323	96	0.98 (0.69–1.37)	0.890	41	1.11 (0.69–1.80)	0.667		40	0.96 (0.60–1.53)	0.856	
Past prostatectomy												
No	604	181	Ref		77	Ref			77	Ref		
Yes	30	9	1.00 (0.43–2.16)	0.997	5	1.48 (0.49–3.69)	0.458		3	0.76 (0.18–2.22)	0.648	
Body mass index												
≥ 22	346	99	Ref		47	Ref			37	Ref		Ref
< 22	288	91	1.15 (0.82–1.62)	0.414	30	1.35 (0.83–2.22)	0.222		43	1.47 (0.92–2.35)	0.111	1.37 (0.84–2.25) 0.210

OR odds ratio, *CI* confidence interval

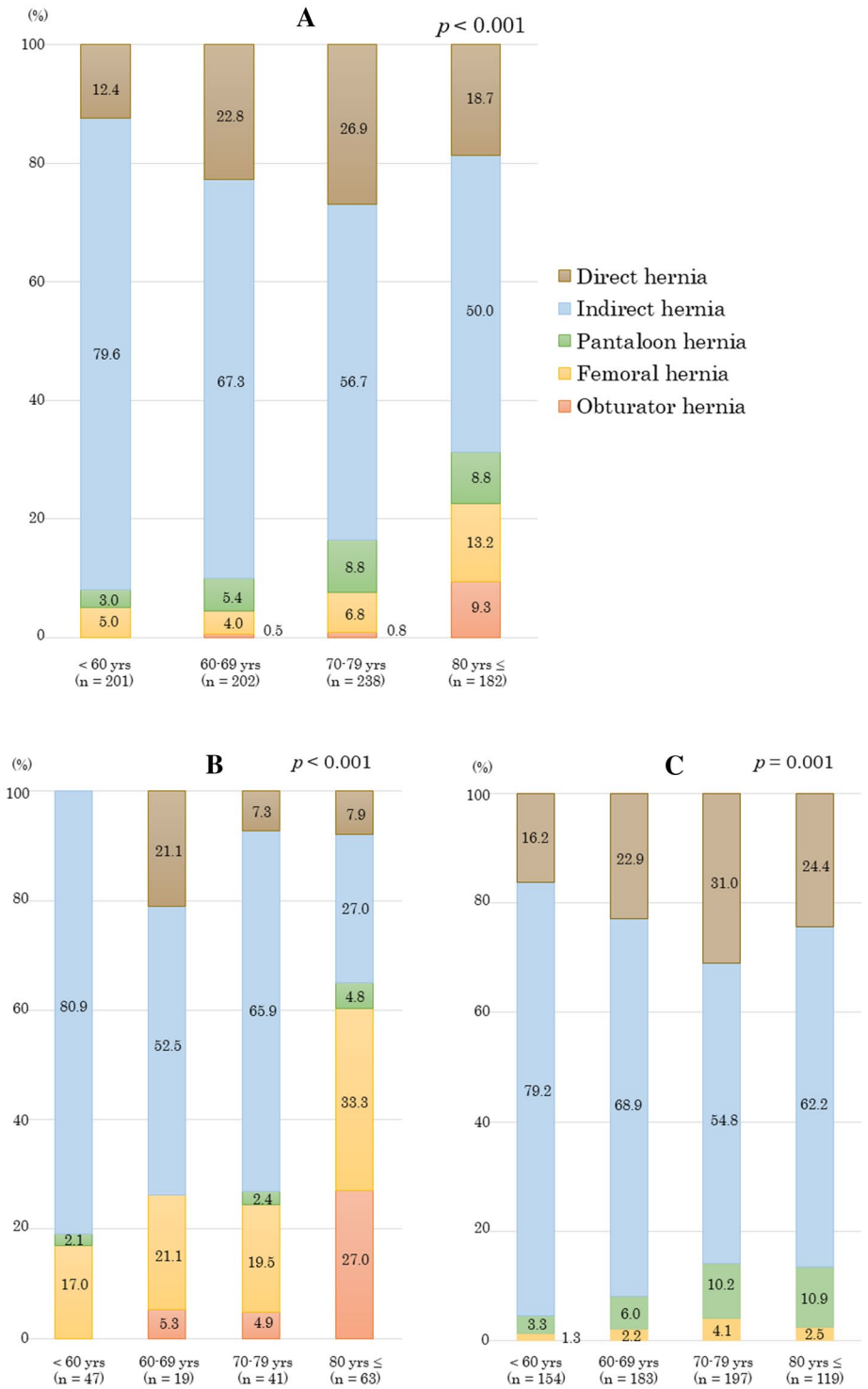

Fig. 1 Cumulative incidence of groin hernia stratified by age. **A** Entire cohort. **B** Female patients. **C** Male patients

A symptomatic inguinal bulge does not necessarily require hernia sac repair. Cord lipomas, which have been identified in about 20% of patients undergoing hernia repair [24, 25], seem to be easily overlooked during TAPP without peritoneal dissection, since one-third of cases do not have a hernia sac. Hence, endoscopic surgeons should keep in mind the possibility of a cord lipoma in patients with symptomatic inguinal swellings without a significant peritoneal protrusion during laparoscopy.

Multiple ipsilateral hernias were observed in a total of 80 patients (12.6%), and their incidence was found to increase consistently with age: from 5.6% for patients aged < 60 years to 21.7% for patients aged 80 years or older. These figures are somewhat higher than the previously reported rate of

Table 5 Univariate and multivariate analyses evaluating predictors of the presence of femoral hernia or obturator hernia

Variables	No. of patients	Univariate analysis			Multivariate analysis	
		n	OR (95% CI)	*p* value	OR (95% CI)	*p* value
Age (years)						
< 80	514	31	Ref		Ref	
≤ 80	120	24	3.90 (2.19–6.93)	< 0.001	3.27 (1.66–6.42)	< 0.001
Gender						
Male	520	16	Ref		Ref	
Female	114	39	16.38 (8.88–31.55)	< 0.001	11.58 (5.33–25.14)	< 0.001
Pulmonary disease						
No	583	52	Ref			
Yes	51	3	0.64 (0.15–1.82)	0.437		
Diabetes mellitus						
No	579	53	Ref		Ref	
Yes	55	2	0.37 (0.06–1.25)	0.123	0.78 (0.15–3.91)	0.756
Smoking habit						
No	311	41	Ref		Ref	
Yes	323	14	0.30 (0.15–0.55)	< 0.001	1.05 (0.47–2.37)	0.907
Past prostatectomy						
No	604	54	Ref			
Yes	30	1	0.35 (0.02–1.69)	0.231		
Body mass index						
≥ 22	346	9	Ref		Ref	
< 22	288	46	7.12 (3.58–15.79)	< 0.001	4.29 (1.96–9.43)	< 0.001

OR odds ratio, *CI* confidence interval

4.6% during laparoscopic TAPP or TEP repairs described by Ramshow et al. [21] or that of 6% observed during herniography and reported by Ekberg et al. [20]. One possible explanation for this discrepancy is likely due to the patients' age: the former study might have enrolled a large number of young patients, since the median age of the enrolled patients was less than 50 years, although the latter one did not clearly state the patients' ages.

We found clinically important differences between men and women in terms of the profile of multiple ipsilateral hernias: (1) the prevalent form was a pantaloons hernia in men, with an incidence of about 70% across all age groups, whereas the prevalent form in women was a groin hernia in which one component was a femoral hernia, an obturator hernia, or both; and (2) the incidence of multiple ipsilateral hernias in which one of the components was a femoral hernia was significantly higher in women than in men (18.4% versus 11.3%, $p = 0.048$, Table 4), although the difference did not reach statistical significance in a multivariate analysis. This result was similar to the previous study, which reported that unsuspected femoral hernias were relatively common in women [26].

As for the body mass index, some previous studies have suggested that an increased weight, along with a higher BMI, is associated with a decreased risk of requiring a groin hernia repair, compared with the risk in normal-weight individuals [27, 28]. Similarly, the incidence of groin hernia repairs in women has been reported to decrease with an increasing BMI among women [29]. Interestingly, the present study showed that the body mass index was not associated with the presence of multiple groin hernias.

Both femoral hernias and obturator hernias are relatively rare types of groin hernias, with incidences of 2–3% [3, 30, 31] and 0.05–0.07%, respectively [32, 33], and are more common in women than in men, with female/male ratios of 7:3 [3, 31] and 5.3:1, respectively [34]. The incidences of these hernias reportedly increase steadily with age and peak during the 9th and 8th decades of life, respectively [3, 34]. The presently reported study yielded similar results. Considering the independent predictors of femoral hernia or obturator hernia identified in this study, the possible presence of these types of hernias should be kept in mind, especially in emaciated female patients who are 80 years old or older. Since information on the management of groin hernias in women is scarce [35], the present study could provide important insights into the treatment of women with groin hernias in daily clinical practice.

A unique characteristic of obturator hernias is their bilateral occurrence in combination with a femoral hernia either unilaterally or bilaterally [36]. Among patients with an obturator hernia in the present study, 54% had bilateral obturator hernias; all of these patients were 80 years or older, and

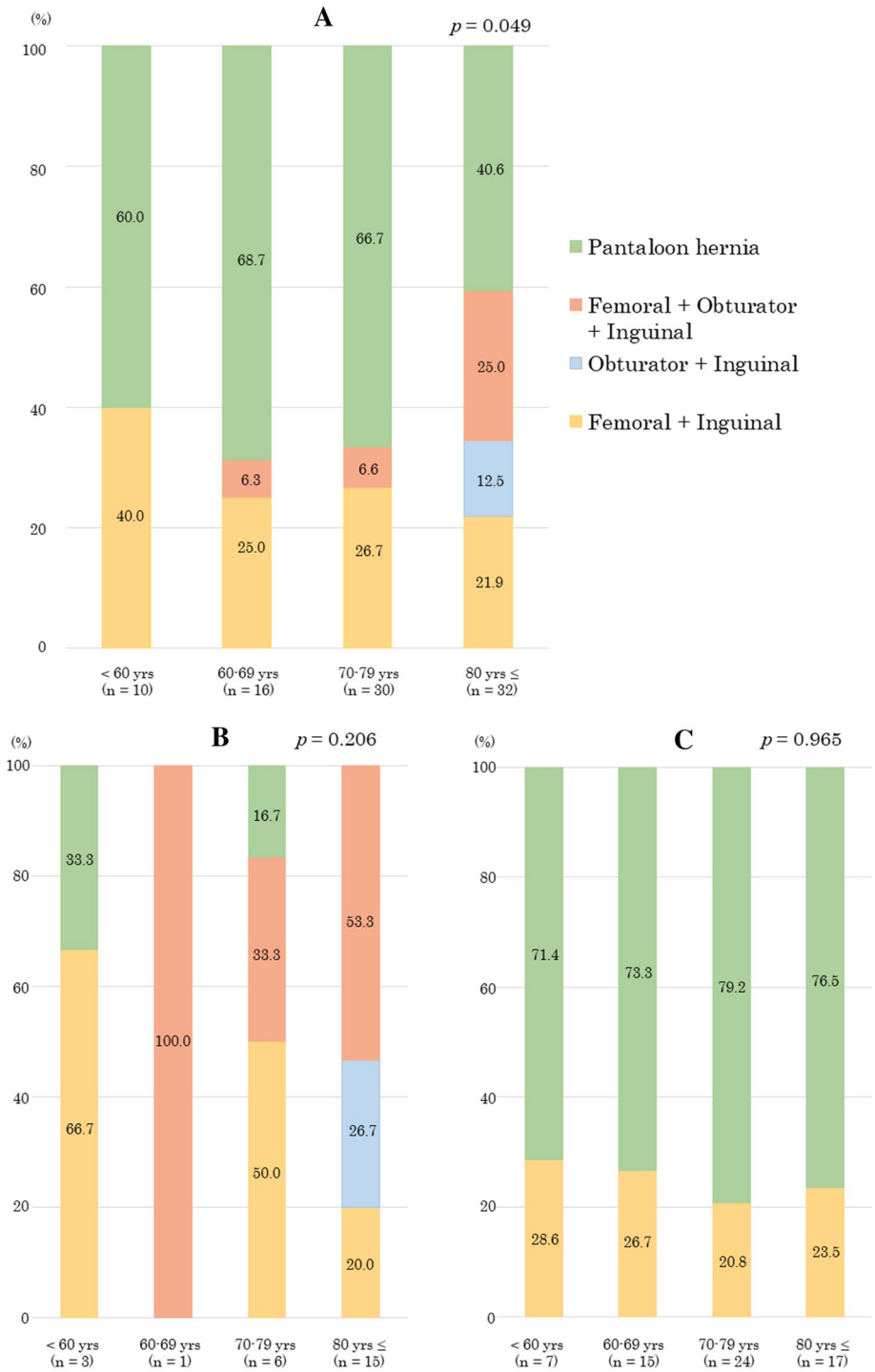

Fig. 2 Type of multiple ipsilateral hernias stratified by age. **A** Entire cohort. **B** Female patients. **C** Male patients

77% had a simultaneous femoral hernia (data not shown). Considering these results, bilateral scrutiny of the entire groin region is indispensable for patients who are diagnosed as having an obturator hernia or those with a groin hernia who have predisposing factors for an obturator hernia, such as an advanced age, nutritional wasting, and a female gender [32, 37]. To this end, laparoscopic TAPP hernia repair is a useful treatment option for obturator hernia, since it allows both the assessment and repair of occult groin hernias simultaneously.

Strengths and weaknesses of the present study

A strength of this study is that the inspection of bilateral myopectineal orifices was systematically performed using laparoscopy in all the enrolled patients. However, our results

Table 6 Incidence of occult contralateral hernia in previous reports

Author	Year	Country	Procedure	No. of patients with OCH	No. of patients: total/diagnosed with ULH	Incidence of OCH (%): per total patients/per patients diagnosed with ULH
Panton et al. [9]	1994	Canada	TAPP	20	79/73	25.3/27.4
Evans et al. [10]	1996	UK	TAPP	12	114/105	10.5/11.4
Sayad et al. [11]	2000	USA	TEP	62	724/552	8.6/11.2
Koehler et al. [12]	2002	USA	TEP	9	100/69	9.0/13.0
O'Rourke et al. [13]	2002	USA	TEP	22	99/51	22/43.1
Bochkarev et al. [14]	2007	USA	TEP	22	–/100[a]	–/22.0
Novitsky et al. [15]	2007	USA	TAPP	19	262/173	7.3/11.0
Griffin et al. [16]	2010	UK	TAPP	45	306/206	14.7/21.8
Pawanindra et al. [17]	2010	India	TEP	13	75/50	17.3/26.0
van den Heuvel et al. [18]	2013	Netherlands	TAPP	218	–/1681[a]	–/13.0
Wu et al. [19]	2016	Taiwan	TEP	23	–/68[a]	–/33.8
Current series	2017	Japan	TAPP	77	634/562	12.1/13.7

ULH unilateral hernia, *OCH* occult contralateral hernia, *TAPP* transabdominal preperitoneal, *TEP* totally extraperitoneal

[a]Including patients diagnosed as having a unilateral hernia

should be interpreted with the following limitations. First, since the study population included only Japanese patients, it might be difficult to extrapolate our results to patients in other countries. Second, this was a retrospective study that included a relatively small number of patients, suggesting that some potential biases might exist. Despite these limitations, we believe that the present study could offer useful information regarding the daily clinical treatment of groin hernias, especially in the elderly.

In conclusion, the multiple occurrence of groin hernias was a clinical feature in the elderly. No matter how many hernia repairs an experienced surgeon has performed, an individual patient can still provide seemingly endless variations on the common theme [38], and surgeons should consider the association between age and the type of groin hernia as described in the present study.

Compliance with ethical standards

Disclosures Kentaro Fukushima, Takahide Yokoyama, Shiro Miwa, Hiroaki Motoyama, Takuma Arai, Noriyuki Kitagawa, Akira Shimizu, Tsuyoshi Notake, Toshiki Kikuchi, Akira Kobayashi, and Shin-ichi Miyagawa have no conflicts of interest or financial ties to disclose.

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