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Perioperative morbidity and mortality of octogenarians treated by radical cystectomy—a multi-institutional retrospective study in Japan

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Abstract

Objective: To determine the characteristics of 90-day morbidity and mortality after radical cystectomy in Japanese octogenarians.

Methods: A retrospective multi-institutional study. We reviewed the records of 834 patients treated by open radical cystectomy between 1997 and 2010. All complications within 90 days after surgery were sorted into the 11 categories proposed by the Memorial Sloan-Kettering Cancer Center and graded according to the modified Clavien-Dindo system. We compared the characteristics of complications between ≥80-year (n = 86) and <80-year (n = 748) groups. Multivariate regression models were used to determine the predictors of complications.

Results: American Society of Anesthesiologists score III–IV was more frequent (14% vs. 6%, respectively, $P < 0.0001$), and ureterocutaneostomy was more frequently performed (30% vs. 21%, respectively, $P = 0.0148$) in the ≥80-year group compared with <80-year group. There were no significant differences in the rates of any complication, major (Grade 3–5) complication, or 90-day mortality between the two groups (≥80-year group: 70%, 21%, 3.5%, respectively, <80-year group: 68%, 22%, 2%, respectively). The ≥80-year group had fewer genitourinary complications (7% vs. 16%, respectively, $P = 0.0131$). Multivariate regression analyses revealed that bowel-using urinary diversion ($P = 0.0031$) and the operative time ($P = 0.0269$) were significant predictors of any grade of complications, and a male sex ($P = 0.0167$), annual cystectomy volume ($P = 0.0284$) and prior cardiovascular comorbidity ($P = 0.0034$) were significant predictors of major complications.

Conclusions: In our experience, radical cystectomy in Japanese octogenarians caused similar perioperative comorbidities. Old age as a single criterion should not be used to abandon radical cystectomy; careful preoperative assessment is mandatory.

Key words: octogenarian, complication, radical cystectomy, morbidity, mortality

Introduction

Because of the progressive increase of the aging population, especially in developed countries, appropriate medical treatments for elderly people are becoming a marked concern in daily clinical practice. In Japan, according to 2014 population estimates, 25.9% of the population is above the age of 65 (Ministry of Internal Affairs and Communication, Statistics Bureau, http://www.stat.go.jp/english/data/nenkan/1431-02.htm). Furthermore, according to projections of the population based on the present fertility rate, those above this age will account for 40% of the population by 2060.

In urological surgery, radical cystectomy (RC) is associated with high levels of morbidity and mortality, and, so far, RC for the elderly has been reported to be associated with higher but acceptable morbidity and mortality (1–5). For example, Donat et al. reported in the Memorial Sloan-Kettering Cancer Center series that octogenarians had a higher incidence of minor (55% vs. 50%, respectively), and major (17% vs. 13%, respectively) complications than a younger cohort, but the differences were not significant (1). However, in a study derived from Surveillance Epidemiology and End Results database study, Hollenback et al. observed that only 12% of octogenarians with invasive cancer underwent extirpative surgery (6), which suggested that concern over complications/mortality risk associated with RC might drive physicians to select conservative treatments for octogenarians before a thorough health status assessment. For further understanding of complications/mortality risk associated with RC in octogenarians, we consider that data collection in a standardized manner is still warranted. In the current study, using a standardized method reported by Shabsigh et al. (7), where the complications were grouped into 11 categories to allow comparison with different cohorts, we performed a comparative study of the type, incidence, and severity of complications occurring within 90 days after RC between octogenarian and younger groups.

Patients and methods

Each institutional review board approved the review of the medical charts of 928 patients (pts) with muscle-invasive or high-grade non-invasive bladder cancer undergoing open RC at Hokkaido University Hospital and 20 affiliated institutions between 1997 and 2010. We collected information on the backgrounds, perioperative outcomes, and 90-day morbidity events after surgery, and previously published a paper on the total cohort (8). In the present study, in order to homogenize the cohort, we excluded the 94 pts receiving simultaneous nephroureterectomy, and the remaining 834 pts treated by RC were included. In terms of grouping the complications, we categorized those into the 11 categories developed by the Memorial Sloan-Kettering Cancer Center (MSKCC) (7). The 11 categories were as follows: gastrointestinal, infectious, wound, genitourinary, cardiac, pulmonary, bleeding, thromboembolic, neurological, miscellaneous and surgical. In terms of the severity, each morbidity was graded according to the Clavien-Dindo grading system (9). In addition, for the severity of ileus, according to the new Japan Clinical Oncology Group (JCOG) postoperative complication criteria, where the 72 most common postoperative complications are defined in detail according to the general grading rules of the Clavien-Dindo classification (10), we allocated Grade 3 to the complication of gastro-enteric tube (long tube) decompression, which was a common conservative treatment method for ileus in Japan (11), although we applied each investigator's grading in the first paper. Thereafter, we compared the incidence, type, and grading of 90-day morbidity between an octogenarian cohort ($n = 86$) and a younger cohort ($n = 748$). In terms of our treatment decision and perioperative care, the method of urinary diversion was determined based on discussions between the patient and physician, and the template of lymphadenectomy was determined by each physician. Regarding perioperative management, an intermittent pneumatic compression pump and/or stockings were used for the prevention of deep vein thrombosis without the routine use of prophylactic anticoagulation. In general, second-generation cephalosporins were prophylactically dripped for 3–4 days. Oral feeding was initiated earlier in the later study period based on the enhanced recovery after surgery (ERAS) protocol (12,13).

Statistical analyses

Comparisons between the two groups were performed using Mann–Whitney U and χ^2 tests. Logistic regression analyses were performed to clarify factors predicting that patients would develop complications. The characteristics analyzed were the sex, age (continuous and ≥80 vs. <80 years), American Society of Anesthesiologists (ASA) score, body mass index (BMI), average annual cystectomy volume (<5 per year vs. 5 ≤ annual volume <10 per year vs. ≥10 per year), history of cardiovascular disease (including hypertension), history of diabetes mellitus, previous surgery, pulmonary disease, and cerebrovascular disease, organ-confined disease, urinary diversion methods (ileal conduit or neobladdder vs. others), operative time (≥400 vs. <400 min) and blood loss (>1300 vs. <1300 mL). All calculations were performed using JMP® version 12.01. P values <0.05 were considered significant.

Results

Patient characteristics

Table 1 summarizes patient characteristics divided by age. Cardiovascular comorbidity was more common in the ≥80-year group than in the <80-year group (63%, 54/86 and 39%, 292/748, respectively, $P <$ 0.0001). In terms of urinary diversion, ureterocutaneostomy was selected more frequently in the ≥80-year group than in the <80-year group (30%, 26/84 and 21%, 155/748, respectively, $P = 0.0148$). As reported previously, 1 hospital was categorized as high-volume, 7 as moderate-volume and 13 as low-volume (8).

Perioperative complications

In the present cohort, 571 (68%, 571/834) patients had at least one complication within 90 days of RC. There was no significant difference in the complication rates between the ≥80-year group and <80-year group (≥80-year group: 70%, 60/86, <80-year group: 68%, 511/748, $P = 0.783$). Table 2 summarizes complications in the two groups. The ≥80-year group had fewer genitourinary complications (7%, 6/86 vs. 16%, 122/748, respectively, $P = 0.0131$). Regarding major complications (Grade 3–5), 186 (22%, 186/834) patients experienced them, and no significant difference in the rate was observed between the two groups (≥80-year group: 21%, 18/86, <80-year group: 22%, 168/748, $P = 0.7453$). Concerning the re-operation rate, there was no significant difference between the two groups (≥80-year group: 14%, 12/86, <80-year group: 11%, 83/748, $P = 0.4418$). Supplementary Table 1 summarizes the major complications and categories in the two groups. Again, fewer genitourinary complications were observed in the ≥80-year group (1.2%, 1/86 vs. 6.3%, 47/748, respectively, $P = 0.0218$). There were 18 deaths within 90 days after surgery. No intraoperative death was observed. Overall, eight patients died from cancer progression after surgery, four patients from gastrointestinal events, two from pulmonary events, two from hemorrhagic events, one from a cardiovascular event, and one from an infection-related event, respectively. In the ≥80-year group, one patient died from a gastrointestinal event, one from a hemorrhagic event, and one from an infectious event. The 30-day mortality rate was 2.3% (2/86) in the ≥80-year group and 0.5% (4/748) in the <80-year group ($P = 0.1257$), and the 90-day mortality

Table 1. Patient characteristics according to age group

Variables	Total, $n = 834$	≥80 years, $n = 86$	<80 years, $n = 748$	*P* value
Sex, *n* (%)				
Male	642 (77%)	64 (74%)	578 (77%)	0.5559
Female	192 (23%)	22 (26%)	170 (23%)	
Age (years), median (range)	70 (25–89)	82 (80–89)	69 (25–79)	<0.0001
Body mass index (BMI) (kg/m^2), $n = 797$				
Median (range)	23 (14.6–35.1)	21.7 (16.4–28.6), $n = 85$	23.2 (14.6–35.1), $n = 712$	0.0002
Average annual cystectomy volume				
High (10 ≤ per year), 1 hospital	122 (15%)	16 (19%)	106 (14%)	0.0413
Moderate (5–10 per year), 7 hospitals	366 (44%)	45 (52%)	321 (43%)	
Low (5≥ per year), 13 hospitals	346 (41%)	25 (29%)	321 (43%)	
No. American Society of Anesthesiologists (ASA) score (%)				
I	296 (35%)	10 (12%)	286 (38%)	<0.0001
II	408 (49%)	64 (74%)	344 (46%)	
III–IV	54 (6%)	12 (14%)	42 (6%)	
Unknown	76 (9%)	0	76 (10%)	
No. prior cardiovascular comorbidity (%)	346 (41%)	54 (63%)	292 (39%)	<0.0001
No. prior surgical history (%)	139 (17%)	13 (15%)	126 (17%)	0.6803
No. prior pulmonary comorbidity (%)	44 (5%)	8 (9%)	36 (5%)	0.105
No. prior cerebrovascular comorbidity (%)	46 (6%)	9 (10%)	37 (5%)	0.0537
No. prior diabetes mellitus comorbidity (%)	131 (16%)	14 (16%)	117 (16%)	0.923
No. neoadjuvant chemotherapy (%)	29 (3%)	2 (2%)	27 (4%)	0.5139
No. form of urinary diversion (%)				
Ileal conduit	477 (57%)	47 (55%)	430 (57%)	0.0148
Neobladder	169 (20%)	11 (13%)	158 (21%)	
Ureterocutaneostomy	181 (22%)	26 (30%)	155 (21%)	
Nephrostomy	3 (0.4%)	2 (0.2%)	1 (0.1%)	
Not performed	4 (0.5%)	0	4 (0.5%)	
Operative time (minutes), $n = 812$				
Median (range)	390 (100–862)	330.5 (130–670), $n = 84$	400 (100–862), $n = 728$	<0.0001
Estimated blood loss (mL), $n = 813$				
Median (range)	1298 (100–19 500)	1200 (165–19 500), $n = 86$	1300 (100–11 300), $n = 727$	0.2929
No. organ-confined disease (%), $n = 823$	455 (55%)	42 (49%)	413 (56%)	0.205
Postoperative hospital stay (days), $n = 813$				
Median (range)	40 (3–364)	39 (3–141), $n = 86$	40 (11–364), $n = 727$	0.0553

rate was 3.5% (3/86) in the ≥80-year group and 2% (15/748) in the <80-year group ($P = 0.405$).

Predictors of complications

Tables 3 and 4 show the results of logistic regression analyses. Urinary diversion methods ($P = 0.0031$) and the operative time ($P = 0.0269$) were significant predictors of any grade of complications in the multivariate model (Table 3). For major complications, male sex ($P = 0.0167$), annual cystectomy volume ($P = 0.0284$) and prior cardiovascular comorbidity ($P = 0.0034$) were significant on multivariate analysis (Table 4).

Discussion

We previously reported that 68% (635/928) of patients experienced at least one 90-day complication, and 17% (156/928) experienced major complications (8). In the present study, excluding patients with simultaneous nephroureterectomy, we compared the postoperative comorbidity and mortality occurring within 90 days after RC between octogenarian and younger groups. Recently, 90-day estimates of comorbidity and mortality have been the most frequently used. A potential background factor would be that recent improvements in perioperative management have postponed surgery-related complications, especially death events. Isbarn et al. also reported in the SEER data that 30-, 60- and 90-day perioperative mortality rates were 1.1%, 2.4% and 3.9%, respectively, and 90-day rates would be the most meaningful assessments (14). As a result, we observed that there was no significant difference in the incidence or severity of postoperartive complications between the two groups. Regarding perioprerative mortality in the octogenarians undergoing RC, Izquierdo et al. reviewed the previous studies, and reported that the mortality rate among series varied widely from 0 to 14% (2). Hence, the present mortality rate in the Japanese octogenarians was in the lower range of the previous series (30-day mortality: 2.3%, 90-day mortality: 3.5%). To our knowledge, this is the largest study of perioperative morbidity and mortality of octogenarians in an Asian cohort. We consider that one of the main reasons for our low mortality would be the low incidence of cardiac (1.2%, 1/86) or absence of thromboembolic events, compared with the higher incidence reported in Western centers (1,15). Iwai et al. also observed a low incidence of cardiac (3/193; 1.6%) and thromboembolic (1/193; 0.5%) events in another Japanese cohort (16). The long postoperative stay (40 days) in our study, probably influenced by universal health coverage, which allows for long admission with an affordable self-pay burden, and the lower BMI (median, 23.0 kg/m^2) might also have had some impact on the mortality rate in the current cohort. Because there would be hidden patients managed non-surgically due to their unfitness for RC, our observation of the equivalent morbidity between the two groups might indirectly support the

Table 2. Summary of complications and categories according to age group

Category	Total, $n = 834$	≥80 years, $n = 86$	<80 years, $n = 748$	P value	Complication	Frequency		
						Total	≥80 years	<80 years
Gastrointestinal	$n = 216$	$n = 23$	$n = 193$	0.8507	Ileus	189	22	167
					Bowel leak	14	0	14
					Gastrointestinal bleeding	5	0	5
					Clostridium difficile colitis	12	1	11
					Rectal stenosis	1	0	1
					Gastric ulcer	3	0	3
Infectious	$n = 258$	$n = 31$	$n = 227$	0.2848	FUO	25	1	24
					UTI	186	25	161
					Sepsis	11	1	10
					Gastroenteritis	2	0	2
					Cholecystitis	2	0	2
					Iliopsoas muscle abscess	1	1	0
					Other site infection	33	4	29
Wound	$n = 179$	$n = 16$	$n = 163$	0.4889	SSI	162	15	147
					Wound dehiscence	29	4	25
Genitourinary	$n = 128$	$n = 6$	$n = 122$	0.0131	Hydronephrosis	85	6	79
					Urinary leak	34	0	34
					Renal failure	5	0	5
					Necrosis of ileal conduit	5	0	5
Cardiac	$n = 6$	$n = 1$	$n = 5$	0.6336	Arrhythmia	2	0	2
					Ischemic heart disease	2	0	2
					Congestive heart failure	2	1	1
Pulmonary	$n = 12$	$n = 2$	$n = 10$	0.4984	Pneumonia	6	1	5
					Respiratory distress	2	1	1
					Pleural effusion	1	0	1
					Lung edema	2	0	2
					Interstitial pneumonia	1	0	1
Bleeding	$n = 4$	$n = 1$	$n = 3$	0.4019	Anemia requiring transfusion	3	1	2
					Wound hematoma	1	0	1
Thromboembolic	$n = 3$	$n = 0$	$n = 3$	0.4186	Deep venous thrombosis	1	0	1
					Pulmonary embolism	2	0	2
Neurological	$n = 15$	$n = 3$	$n = 12$	0.2618	Cerebrovascular event	7	1	6
					Peripheral neuropathy	3	1	2
					Delirium/ Agitation	5	1	4
Miscellaneous	$n = 21$	$n = 1$	$n = 20$	0.3498	Lymphocele	2	0	2
					Dermatitis	2	0	2
					Liver dysfunction	3	0	3
					Other rare complications	14	1	13
Surgical	$n = 6$	$n = 1$	$n = 5$	0.6336	Rectal injury	3	0	3
					Incisional hernia	3	1	2

recent concept of comprehensive geriatric assessment in older patients with cancer, not solely based on the chronological age (17). Old age as a single criterion should not be used to abandon RC; careful preoperative assessment of the overall health status is mandatory.

In the present comparative study of categories between octogenarian and younger groups, fewer genitourinary complications were observed in the octogenarians for both all and major complications, due to reduced hydronephrosis and the absence of urinary leak, renal failure, and necrosis of the ileal conduit. As described previously, the more frequent performance of ureterocutaneostomy in the octogenarian cohort would have a marked impact on that difference in the incidence of genitourinary complications. Donat et al. previously reported that they observed a significantly higher rate of neurological and cardiac complications (10.3% vs. 3.9%, $P = 0.01$ and 19.7% vs. 9.5%, respectively, $P = 0.006$) in an octogenarian compared with younger cohort (1). Racial differences, a prospectively constructed database, data from a single high-volume center and the dominance of an ileal conduit (97%) in their octogenarian cohort would be potential reasons for the difference in observations.

In terms of risk factors for postoperative complications, urinary diversion methods ($P = 0.0031$) and the operative time ($P = 0.0269$) were significant predictors of any grade of complications in the multivariate model. We consider that these observations indirectly support the concept of avoiding the use of the bowel for urinary diversion in vulnerable patients. Actually, in the present cohort, ureterocutaneostomy was performed more frequently, and the total operative time was significantly shorter in the ≥80-year group than in the <80-year group. Recently, Berger et al. reported a significantly lower overall rate of severe complications in a ureterocutaneostomy group (11.5%) compared with patients undergoing bowel-using diversion (25%) ($P = 0.03$) in those aged 75 years or older, and noted the need to reconsider ureterocutaneostomy in vulnerable patients (18). As major complications, prior cardiovascular comorbidity ($P = 0.0034$), the annual cystectomy volume ($P = 0.0284$) and male sex ($P = 0.0167$) were significant on multivariate

Table 3. Univariate and multivariate analyses of all complications

Variables analyzed	No. of patients	Univariate anlysis		Mutivariate analysis	
		Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Sex					
Male	642	1.503 (1.071–2.101)	0.0186	1.363 (0.959–1.928)	0.0837
Female	192	1		1	
Age					
≥80	86	1.070 (0.666–1.764)	0.783		
<80	748	1			
Continuous		1.015 (1.000–1.031)	0.0469	1.016 (0.999–1.034)	0.0678
ASA score					
≥II	462	1.656 (1.208–2.271)	0.0018	1.362 (0.948–1.956)	0.0944
I	296	1			
BMI (kg/m^2)					
≥25	216	1.243 (0.883–1.767)	0.2146		
<25	581	1			
Average annual cytectomy volume					
High (10 ≤ per year)	122	0.992 (0.640–1.555)	0.9715		
Moderate (5–10 per year)	366	1.030 (0.751–1.414)	0.8532		
Low (5≥ per year)	346	1			
Prior cardiovascular comorbidity					
Yes	346	1.721 (1.270–2.343)	0.0004	1.393 (0.983–1.980)	0.0624
No	488	1		1	
Prior surgical history					
Yes	139	1.388 (0.928–2.116)	0.112		
No	695	1			
Prior pulmonary comorbidity					
Yes	44	1.242 (0.645–2.547)	0.5267		
No	790	1			
Prior cerebrovascular comorbidity					
Yes	46	2.681 (1.258–6.624)	0.0091	2.128 (0.976–5.342)	0.0581
No	788	1		1	
Prior diabetes mellitus comorbidity					
Yes	131	1.394 (0.920–2.159)	0.1191		
No	692	1			
Organ-confined disease					
No	368	0.903 (0.671–1.216)	0.5021		
Yes	455	1			
Types of urinary diversion					
Ileal conduit or neobladder	646	1.820 (1.298–2.545)	0.0005	1.768 (1.213–2.578)	0.0031
Others	188	1		1	
Operative time (minutes)					
≥400	389	1.546 (1.145–2.093)	0.0044	1.448 (1.043–2.015)	0.0269
<400	423	1		1	
Estimated blood loss (mL)					
≥1300	406	1.185 (0.880–1.597)	0.2646		
<1300	407	1			

analysis. The significance of prior cardiovascular comorbidity was consistent with our previous observation (8). Regarding the effect of the surgical volume on the morbidity rate, this was well-established in previous studies (19,20). For example, Leow et al., using an all-payer hospital discharge database in the USA, reported that surgeons performing ≥7 RCs/year had 45% lower odds of encountering major complications (odds ratio: 0.55: $P < 0.001$) compared with surgeons performing one RC/year (21). In terms of sex differences, we do not have an adequate explanation. In contrast, Siegrist et al. reported that their female cohort showed a significantly higher rate of complications (22).

The Clavien-Dindo classification for postoperative complications has been widely used and it enables us to compare surgical outcomes from different institutes. However, the inter-observer variability inherent in the classification was also recognized because of its general criteria (23,24). For example, long-tube decompression is frequently used for the conservative management of postoperative ileus in Japan, which reaches the distal small bowel beyond the Treiz ligament. However, the original Clavien-Dindo classification does not define specific grading. As mentioned in Materials and Methods, according to the JCOG criteria, we allocated Grade 3 to postoperative ileus treated by long-tube decompression and Grade 2 to that treated with a nasogastric tube (short tube), which resulted in a higher major complication rate of 22% than our previous observation (17%). In the present series, 57 patients underwent long-tube decompression, and, in 86% (49/57) of the patients, Grade 2 had been allocated by the original grader. We agree that detailed grading

Table 4. Univariate and multivariate analyses of major complications

Variables analyzed	No. of patients	Univariate anlysis		Mutivariate analysis	
		Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Sex					
Male	642	1.653 (1.094–2.565)	0.0164	1.660 (1.094–2.586)	0.0167
Female	192	1		1	
Age					
≥80	86	0.914 (0.515–1.548)	0.7453		
<80	748	1			
Continuous		1.015 (0.997–1.033)	0.0953		
ASA score					
≥II	462	1.229 (0.864–1.761)	0.2522		
I	296	1			
BMI (kg/m^2)					
≥25	216	1.209 (0.836–1.732)	0.3095		
<25	581	1			
Average annual cytectomy volume					
High (10 ≤ per year)	122	0.536 (0.290–0.940)	0.0288	0.533 (0.287–0.938)	0.0284
Moderate (5–10 per year)	366	1.228 (0.869–1.738)	0.2444	1.176 (0.827–1.674)	0.3669
Low (5≥ per year)	346	1		1	
Prior cardiovascular comorbidity					
Yes	346	1.698 (1.223–2.360)	0.0016	1.645 (1.179–2.298)	0.0034
No	488	1		1	
Prior surgical history					
Yes	139	1.329 (0.867–2.003)	0.1879		
No	695	1			
Prior pulmonary comorbidity					
Yes	44	1.171 (0.555–2.295)	0.6628		
No	790	1			
Prior cerebrovascular comorbidity					
Yes	46	1.567 (0.794–2.946)	0.1881		
No	788	1			
Prior diabetes mellitus comorbidity					
Yes	131	0.782 (0.480–1.233)	0.2973		
No	692	1			
Organ-confined disease					
No	368	0.915 (0.657–1.270)	0.5949		
Yes	455	1			
Types of urinary diversion					
Ileal conduit or neobladder	646	1.458 (0.971–2.242)	0.0697		
Others	188	1			
Operative time (minutes)					
≥400	389	1.213 (0.873–1.686)	0.2504		
<400	423	1			
Estimated blood loss (mL)					
≥1300	406	1.138 (0.820–1.581)	0.4401		
<1300	407	1			

guidelines allow more precise comparative studies of surgical complications (10).

The present study had several limitations, including its retrospective design. Several minor events might be missed during data extraction. There would be variations in terms of surgical techniques as well as postoperative management among the participating hospitals. Because our multi-institutional database only included patients undergoing RC, we could not calculate the number of octogenarians in whom RC was aborted due to a poor performance status or for whom conservative treatment was selected in the participating hospitals. Several background factors are different from those in Western countries, including the healthcare insurance system in Japan and postoperative management for ileus, which might have influences on our observations. Interestingly, at least in the United States and United Kingdom, decompression with a short tube (nasogastric tube) is the most common conservative management for postoperative ileus, and a long tube is barely selected (personal communication). In addition, a minimum invasive approach has also been introduced to RC in Japan; therefore, we need to re-evaluate the incidence and severity of postoperative complications in the latest cohort. Nevertheless, we believe that the present study generated several important findings.

Supplementary data

Supplementary data are available at *Japanese Journal of Clinical Oncology* online.

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Conflict of interest statement

None declared.

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