How to Choose the Best Procedure Type for Duodenal Neuroendocrine Tumors With a Maximum Diameter of 1 to 2 Cm a Propensity Score Matching Analysis Based on the SEER Database

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Research

Keywords: Duodenal neuroendocrine tumor, SEER, prognosis, surgical approach

Posted Date: July 20th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-42716/v1

Abstract

Background: The treatment plan for duodenal neuroendocrine tumors (d-NETs) with a diameter between 1 and 2 cm is still controversy.

Aim: To compare the effects of local endoscopic resection and radical resection on the prognosis of d-NETs with a maximum diameter of 1-2 cm.

Methods: 286 eligible patients were identified from the SEER database. Propensity score matching (PSM) was done to match patients 1:1 on clinicopathological characteristics. Kaplan-Meier analysis was used to analyze the factors affecting the prognosis.

Results: Before PSM, there was no significant difference in the cancer-specific survival (CSS) between the two groups ($P = 0.595$), but the tumor size, T stage, N stage, and M stage were significantly different between the two groups (all $P < 0.05$). After 1:1 PSM, the differences in clinicopathological characteristics between the two groups were significantly reduced (all $P > 0.05$). Survival analysis showed that only the tumor grade was correlated with the prognosis ($P = 0$); surgical method and other clinicopathological characteristics were not correlated with the prognosis (all $P > 0.05$).

Conclusion: The surgical approach had no significant effect on the prognosis of d-NET patients with a maximum diameter of 1-2 cm and without lymph node metastasis.

Background

Duodenal neuroendocrine tumors (d-NETs), a type of tumor originating from neuroendocrine cells, account for approximately 3% of the total gastrointestinal neuroendocrine tumors. The incidence of d-NETs has increased significantly in recent years with the popularization of endoscopy [1, 2]. Surgical resection is the only treatment that can cure d-NETs. Currently, the choice of surgical regimen is mainly based on tumor size, tissue grading, and the presence of lymph node metastasis on imaging [3, 4]. For tumors < 1 cm in diameter that are not in the periampullary region and that have no suspicious lymph node metastasis, endoscopic resection is recommended. For tumors larger than 2 cm in diameter, radical resection is recommended. For tumors in the periampullary region having different biological behaviors from neuroendocrine tumors (NETs) in other regions, local resection and lymph node biopsy or radical resection are required. However, for tumors with a diameter between 1 and 2 cm, due to the lack of prospective studies and large clinical studies, the specific treatment plan is still not standardized [3, 4]. Therefore, further studies with large sample sizes are needed to confirm whether endoscopic treatment or surgical resection is best.

The Surveillance, Epidemiology, and End Results (SEER) database is a tumor registry database established in the 1970s in the United States, covering approximately 28% of cancer patients in the United States. The database provides important data support for clinical research and clinical decision-making. However, since the SEER database includes data from multiple cancer registration centers, the real-world

noncontrolled data are imbalanced to a certain extent and have many missing values. To balance the baseline characteristics between groups, this study collected the clinicopathological and prognostic data of d-NET patients with a tumor of 1–2 cm in diameter in the SEER database. The propensity score matching (PSM) method was used to match the characteristics between the groups to investigate whether radical resection improved the long-term prognosis of patients.

1. Data And Methods

1. The data for pathologically diagnosed d-NET patients from 2004 to 2016 were collected from the SEER database (site code: C17.0-Duodenum. ICD-O-3 histology code, 8240: Carcinoid tumor, 8246: Carcinoid carcinoma). All patients with a tumor of 1–2 cm in diameter who underwent local resection (RX Summ-Surg Prim Site (1998+) codes 20–27) or radical resection (codes 30, 40, and 60) were enrolled. Exclusion criteria: (1) the tumor grade was unknown or undifferentiated and anaplastic for Grade IV; (2) lymph node metastasis or distant metastasis was unknown; (3) the cause of death was unclear or death was not tumor-related; (4) the d-NET was combined with other tumors; (5) since our aim was looking at long-term outcomes, we excluded patients who died from surgery or whose survival time was less than 1 month. Due to the strict register-based nature of the study, informed consent was waived. Moreover, the study was exempted from Institutional Review Board approval, in view of the SEER's use of unidentifiable patient information.

1. 1.2 Demographic characteristics, such as sex, age, race, and marital status, and pathological characteristics, such as tissue grade, tumor stage (T stage), and node stage (N stage), were collected. According to detailed information such as tumor size and local extension provided by the SEER database, the TNM status of patients was rejudged according to the 7th edition of the American Joint Committee on Cancer (AJCC) staging system. All data collection and statistical calculations were independently completed by two authors (Jiebin Xie and Huanyu Tang).
2. 1.3 Statistical analysis

Cancer-specific survival (CSS) was taken as the study endpoint. The chi-squared test or t test was used to quantify the differences between surgical groups. The Kaplan-Meier method was used for survival analysis. The above statistical analysis was performed using SPSS 22.0. $P < 0.05$ was considered statistically significant. The MatchIt package of R software v3.6.3 was used to perform the 1:1 PSM with a caliper value set to 0.1. The nearest-neighbor matching method was used to match the baseline characteristic differences between the two groups.

2. Results

2.1 General condition and survival analysis before matching

Data of 3709 pathologically diagnosed d-NET patients from 2004 to 2016 were obtained from the SEER database. After they were screened by the above inclusion and exclusion criteria, 286 d-NET patients met the inclusion criteria, including 130 patients with local resection and 156 patients with radical resection

(Fig. 1). Among all tumors, 61.19% were T2, 85.67% were G1, 75.17% were Carcinoid tumor (ICD-O-3 histology code: 8240). The total N1 proportion was 22.03%, including 35.9% in the radical resection group and 4.62% in the local resection group (Table 1). The final follow-up time was November 2018. The overall 5-year CSS was 93.2 ± 2.1%. The 5-year CSS of patients in the local resection group was 92.9 ± 3.7%. The 5-year CSS of patients in the radical resection group was 93.4 ± 2.3%. Kaplan-Meier survival analysis showed no significant difference in survival rate between the two groups before PSM ($P = 0.595$, Fig. 3a).

Table 1
Distribution profiles of the clinicopathologic factors of the patients in the local resection group and radical resection group before and after PSM matching

Characteristics	Cases (%)	Before PSM			After PSM		
		LR (n = 130)	RR (n = 156)	*P*-value	LR (n = 77)	RR (n = 77)	*P*-value
Age, (year x ± s)	62.9 ± 12.2	64.4 ± 12.0	61.7 ± 12.2	0.062	64.8 ± 11.3	64.1 ± 10.6	0.714
Size, (mm x ± s)	13.6 ± 3.4	12.9 ± 3.7	14.2 ± 3.3	0.001	14.0 ± 3.4	13.7 ± 3.4	0.704
Sex				0.086			0.503
Male	158 (55.2)	79 (60.8)	79 (50.6)		51 (66.2)	47 (61.0)	
Female	128 (44.8)	51 (39.2)	77 (49.4)		26 (33.8)	30 (39.0)	
Race				0.162			0.241
White	194 (67.8)	84 (64.6)	110 (70.5)		48 (62.3)	55 (71.4)	
Black	74 (25.9)	34 (26.2)	40 (25.6)		21 (27.3)	19 (24.7)	
Others	18 (6.3)	12 (9.2)	6 (3.9)		8 (10.4)	3 (3.9)	
Marriage				0.774			0.925
Married	154 (53.9)	73 (56.2)	81 (51.9)		41 (53.2)	43 (55.8)	
Single	118 (41.2)	51 (39.2)	67 (43.0)		30 (39.0)	29 (37.7)	
Unknown	14 (4.9)	6 (4.6)	8 (5.1)		6 (7.8)	5 (6.5)	
Distant metastasis				0.026			0.56
NO	273 (95.5)	128 (98.5)	145 (92.9)		75 (49.7)	76 (50.3)	
Yes	13 (4.5)	2 (1.5)	11 (7.1)		2 (66.7)	1 (33.3)	
Grade				0.231			0.383

Abbreviations: LR, local resection; RR, radical resection; PSM, propensity score matching.

a: International Classification of Diseases for Oncology, 3rd Edition (ICD-O-3): 8240, Carcinoid tumor; 8246, Carcinoid carcinoma.

Characteristics	Cases (%)	Before PSM			After PSM		
		LR (n = 130)	RR (n = 156)	*P*-value	LR (n = 77)	RR (n = 77)	*P*-value
G1	245 (85.7)	116 (89.2)	129 (82.7)		63 (81.8)	68 (88.3)	
G2	36 (12.6)	13 (10.0)	23 (14.7)		13 (16.9)	9 (11.7)	
G3	5 (1.7)	1 (0.8)	4 (2.6)		1 (1.3)	0	
Histologic Type[a]				0.24			1
8240	215 (75.2)	102 (78.5)	113 (72.4)		60 (77.9)	60 (77.9)	
8246	71 (24.8)	28 (21.5)	43 (27.6)		17 (22.1)	17 (22.1)	
N stage							0.513
N0	223 (78.0)	124 (95.4)	99 (63.5)	0	71 (49.3)	73 (50.7)	
N1	63 (22.0)	6 (4.6)	57 (36.5)		6 (60.0)	4 (40.0)	
T stage				0			0.34
T1	78 (27.3)	55 (42.3)	23 (14.7)		15 (19.5)	17 (22.1)	
T2	175 (61.2)	71 (54.7)	104 (66.7)		58 (75.3)	51 (66.2)	
T3	21 (7.3)	2 (1.5)	19 (12.2)		2 (2.6)	7 (9.1)	
T4	12 (4.2)	2 (1.5)	10 (6.4)		2 (2.6)	2 (2.6)	
TNM stage				0			0.909
I	72 (25.2)	54 (41.6)	18 (11.5)		14 (18.2)	16 (20.8)	
II	143 (50.0)	67 (51.5)	76 (48.7)		54 (70.1)	54 (70.1)	
III	58 (20.3)	7 (5.4)	51 (32.7)		7 (9.1)	6 (7.8)	
IV	13 (4.5)	2 (1.5)	11 (7.1)		2 (2.6)	1 (1.3)	
5-year CSS		92.9 ± 3.7	93.4 ± 2.3	0.595	96.2 ± 2.8	98.4 ± 1.6	0.558

Abbreviations: LR, local resection; RR, radical resection; PSM, propensity score matching.

a: International Classification of Diseases for Oncology, 3rd Edition (ICD-O-3): 8240, Carcinoid tumor; 8246, Carcinoid carcinoma.

Characteristics	Cases (%)	Before PSM			After PSM		
		LR (n = 130)	RR (n = 156)	*P*-value	LR (n = 77)	RR (n = 77)	*P*-value
5-year OS		83.3 ± 4.7	87.1 ± 3.2	0.437	84.7 ± 5.6	88.9 ± 4.6	0.198

Abbreviations: LR, local resection; RR, radical resection; PSM, propensity score matching.

a: International Classification of Diseases for Oncology, 3rd Edition (ICD-O-3): 8240, Carcinoid tumor; 8246, Carcinoid carcinoma.

2.2 Comparison of baseline data and the prognosis of the local resection and radical resection groups before and after matching

Before the matching, there was no significant difference in mean age between the local resection group (64.38 ± 12.00 years) and the radical resection group (61.68 ± 12.24 years, $P = 0.062$). The mean tumor size in the local resection group (12.88 ± 3. 6 mm) was significantly smaller than that in the radical resection group (14.20 ± 3. 29 mm, $P = 0.001$). The T stage, the N stage, the M stage, and the TNM stage in the radical resection group were significantly higher than in the local resection group (all $P < 0.05$). The differences in race, marriage, sex, tissue type, and degree of differentiation were not statistically significant between two groups. To eliminate the differences in baseline characteristics between the two groups, PSM was used to balance all clinicopathological valuables and demographic characteristics (Fig. 2). A total of 154 patients were selected according to the chosen 1:1 ratio, including 77 in each group. On this basis, the comparison of patients in the matched groups showed that the differences in clinicopathological characteristics were significantly reduced, and none of the above characteristics were significantly different between two groups after matching (Table 1).

2.3 Survival analysis and subgroup analysis after matching

After matching, the 5-year CSS of patients in the local resection and radical resection groups was 96.2 ± 2.8% and 98.4 ± 1.6%, respectively. Survival analysis showed no significant difference in CSS between the two groups ($P = 0.558$, Fig. 3b). Except for the degree of differentiation ($P = 0$, Fig. 3c), the surgical approach, and other clinicopathological features, such as age, sex, T stage, and tissue type, were not correlated with prognosis (Table 2). Further survival analysis of nonmetastatic d-NET patients with T2 + stage showed that the 5-year CSS was 98.1 ± 8.18% in the local resection group and 97.8 ± 2.2% in the radical treatment group, which was still not significant ($P = 0.973$ Fig. 3d).

Table 2
Factors associated with cancer-specific survival after PSM for duodenal neuroendocrine tumors (d-NETs)

Characteristics	Cases (%)	χ^2	*P*-value
	Total (n = 154)		
Age		2.284	0.131
< 60	48 (31.17)		
≥ 60	106 (68.83)	1.179	0.19
Male	98 (63.64)		
Female	56 (36.36)		
Race		0.239	0.887
White	103 (66.88)		
Black	40 (25.97)		
Others	11 (7.14)		
Marriage		2.296	0.273
Married	84 (54.54)		
Single	59 (38.31)		
Unknown	11 (7.14)		
Distant metastasis		0.058	0.809
NO	151		
Yes	3		
Grade		17.52	0
G1	131		
G2	22		
G3	1		
Histologic type		1.029	0.31
8240	120 (77.92)		
8246	34 (22.08)		
N stage		0.258	0.511
N0	144 (93.51)		

Characteristics	Cases (%)	χ^2	*P*-value
	Total (n = 154)		
N1	10 (6.49)		
T stage		0.447	0.924
T1	32 (20.78)		
T2	109 (70.78)		
T3	9 (5.84)		
T4	4 (2.60)		
TNM stage		0.662	0.882
I	30 (19.48)		
II	108 (70.13)		
III	13 (8.44)		
IV	3 (1.95)		
Surgical procedure		0.344	0.558
Radical resection	77 (50.0)		
Local resection	77 (50.0)		

Discussion

Although d-NET is a rare tumor, the incidence rate in recent years has been rising. Seventy-five percent of d-NET patients have a tumor diameter below 2 cm at the time of initial diagnosis, most of which are confined to the mucosa and submucosa. For nonampullary tumors smaller than 1 cm with better differentiation, lymph node metastasis rates are relatively low, and the current guidelines recommend endoscopic treatment as the main treatment. Patients with a tumor diameter of 1–2 cm have a higher likelihood of distant lymphatic metastasis and a thinner wall in the duodenum than in other gastrointestinal tracts. Therefore, the rate of surgical resection is currently higher for these patients.

Radical resection can more completely remove the primary lesion and the primary foci. However, due to the special location of the duodenum, the risk of radical resection is greater, the treatment cost is high, the hospital stay is longer, and postoperative complications are more common [5–7]. In addition, the differences in the effects of endoscopic vs. surgical treatment on prognosis are still rarely reported. Therefore, there is still much debate about the treatment of d-NET patients with a tumor of 1–2 cm in diameter [3, 4].

Margonis et al. [7] studied 146 d-NET patients undergoing different surgical methods and found that the prognosis of d-NET was correlated with tumor grade and metastasis at the time of diagnosis but was not correlated with the surgical method. Our study showed that among the 286 patients who met the inclusion criteria, there was no significant difference in the CSS between the two groups before matching. However, fewer of our patients underwent endoscopic resection than radical resection, and the endoscopic resection was mainly done in patients with older age, smaller tumors, and N0 tumors. Considering the differences in the clinicopathological characteristics, sample size, and risk factors before treatment between the patients in the local resection group and the radical resection group, which led to the difficulty of balancing the covariates between the groups, PSM was used to control the bias that resulted. PSM can simultaneously match the characteristics of multiple factors, minimize confounding bias, and better simulate clinical studies, especially when we are unable to do a prospective clinical study or the clinical study is low-quality. Analysis based on a large sample size after PSM has more reference value [8]. In the present study, after the PSM, there was no significant difference in the clinicopathological distribution characteristics between the two groups, which improved the reliability of the conclusions of the subsequent analysis.

Endoscopic treatment, as the main treatment method for tumors less than 1 cm, has the significant advantages of short operation time, low cost, short hospital stay, and less impact on quality of life [9]. With the progression of ultrasound endoscopy, endoscopic mucosal resection, and endoscopic submucosal dissection, the advantages of endoscopic resection treatment of gastrointestinal NET tumors have become obvious. The analysis of the endoscopic treatment effect and prognosis of gastrointestinal NET patients by Chen [10] showed that endoscopic submucosal dissection can be used for both en bloc and complete resection of lesions ≤ 3.5 cm, and no new metastasis occurred during the follow-up. Our results showed that after matching, surgical method, age, sex, T stage, and tissue type were not correlated with prognosis, but the degree of differentiation was ($P = 0$), in line with the findings reported by Margonis et al [7]. To further analyze the survival advantage of radical resection in patients with ≥ T2 d-NET the patients with lymph node metastasis or distant metastasis were excluded for stratified analysis, the results still showed that there was no difference in survival between patients with radical resection and local treatment. Local endoscopic treatment is still recommended for G1 patients regardless of sex, age, marital status, and T stage.

However, due to the thin wall of the duodenum and its rich blood vessels, most tumors invade the submucosa. Therefore, duodenal endoscopic submucosal dissection is truly challenging, and even Japanese experts think twice before indicating[11], because there are risks of bleeding, perforation, positive margins, and missed metastatic lymph nodes in endoscopic resection treatment [8, 9, 12–16]. Some studies reported that the lymphatic metastasis rate of d-NET with a tumor of 1–2 cm in diameter was approximately 60% [17, 18]. Our data showed that among the 286 patients included, the T2 rate was 61.19%, which was the highest, the T3 + rate was 11.54%, and the total lymph node positive rate was 22.03%, which included 35.9% of the radical resection group and 4.62% of the local resection group. Our findings are consistent with the reported studies. The earlier studies may have had higher lymphatic metastasis rates because all of their patients underwent radical resection. Combining those data with

ours, approximately 71.33% of d-NET (T1N0, T2N0) patients with a tumor of 1–2 cm in diameter can be treated with local endoscopic resection. However, for patients with T3 + N0, choosing the surgical method is a dilemma. If radical resection is chosen, the risk of surgery is increased, the treatment risk and the length of hospital stays are significantly prolonged[7], and there is no survival benefit over local resection. However, endoscopic treatment also has the risks of perforation, bleeding, and positive resection margin. It is recently reported that endoscopic resection of full-thickness diseased tissue combined with continuous laparoscopic suture treatment has achieved good clinical outcomes in the treatment of d-NETs [19]. This method can completely remove the lesion tissue, while also detecting the presence of swollen lymph nodes and metastatic lesions in the abdominal cavity and strengthen the suture wound. This should be the optimal surgical treatment plan for these patients, but few studies have confirmed its short-term and long-term efficacy; thus, more prospective studies are needed. However, for N + patients, radical resection of metastatic lymph nodes should be the standard treatment.

This study has some limitations. First, it was a retrospective study based on the SEER database, and there are confounding factors of mismatching, such as the difference in surgeon skills and the general condition of the patients. Second, to ensure the integrity of the data, we deleted many cases, so the total sample size was small. In particular, the numbers of N1, T3, and T4 patients after matching were small. Third, the advantages and disadvantages of the two surgical methods are important factors in their long-term and short-term efficacy, but the SEER database does not provide information on postoperative complications, which limits the comparison of the short-term efficacy. Although our data are not ideal, PSM performed a good balancing of the clinical and pathological characteristics of the two groups, reducing the selection bias. We also compared the differences in overall survival (OS) between the two groups and achieved consistent results with previous studies. Our results still need to be validated by a prospective, multicenter, randomized controlled study.

Conclusion

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The surgical approach had no significant effect on prognosis, and the degree of tumor differentiation was an independent prognostic factor in d-NET patients with a maximum tumor diameter of 1–2 cm. Local endoscopic resection is still recommended for G1 patients regardless of factors such as sex, age, marital status, and T stage, but for patients with T3 + N0M0, combined laparoendoscopic full-thickness resection may be the best procedure type in the future.

Abbreviations

d-NETs
duodenal neuroendocrine tumors; PSM:Propensity score matching; CSS:cancer-specific survival; OS:overall survival.

Declarations

Ethics approval and consent to participate

This study was exempted from Institutional Review Board approval, in view of the SEER's use of unidentifiable patient information. Due to the strict register-based nature of the study, informed consent was waived.

Consent for publication

Not applicable

Availability of data and materials

The data were obtained from the SEER database.

Competing interests

The authors declare that they have no competing interests

Funding

This work was supported by The Cooperative Fund of Nanchong Government and North Sichuan Medical College (No. 18SXHZ0357).

Authors' contributions

Huanyu Tang, Jiebin Xie , and Xun Li conceived and designed the study. All data collection and statistical calculations were independently completed by Jiebin Xie and Huanyu Tang. Huanyu Tang and Yueshan Pang drafted the manuscript. Xun Li, Xia Hua and Jiebin Xie critically revised the manuscript for important intellectual content. Yueshan pang and Xia Hua provided supervision All authors have given the final approval of the manuscript for submission and publication.

Acknowledgements

We are very grateful to the staff in Surveillance, Epidemiology, and End Results (SEER) Program for their kind work in data collection and delivery.

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Figures

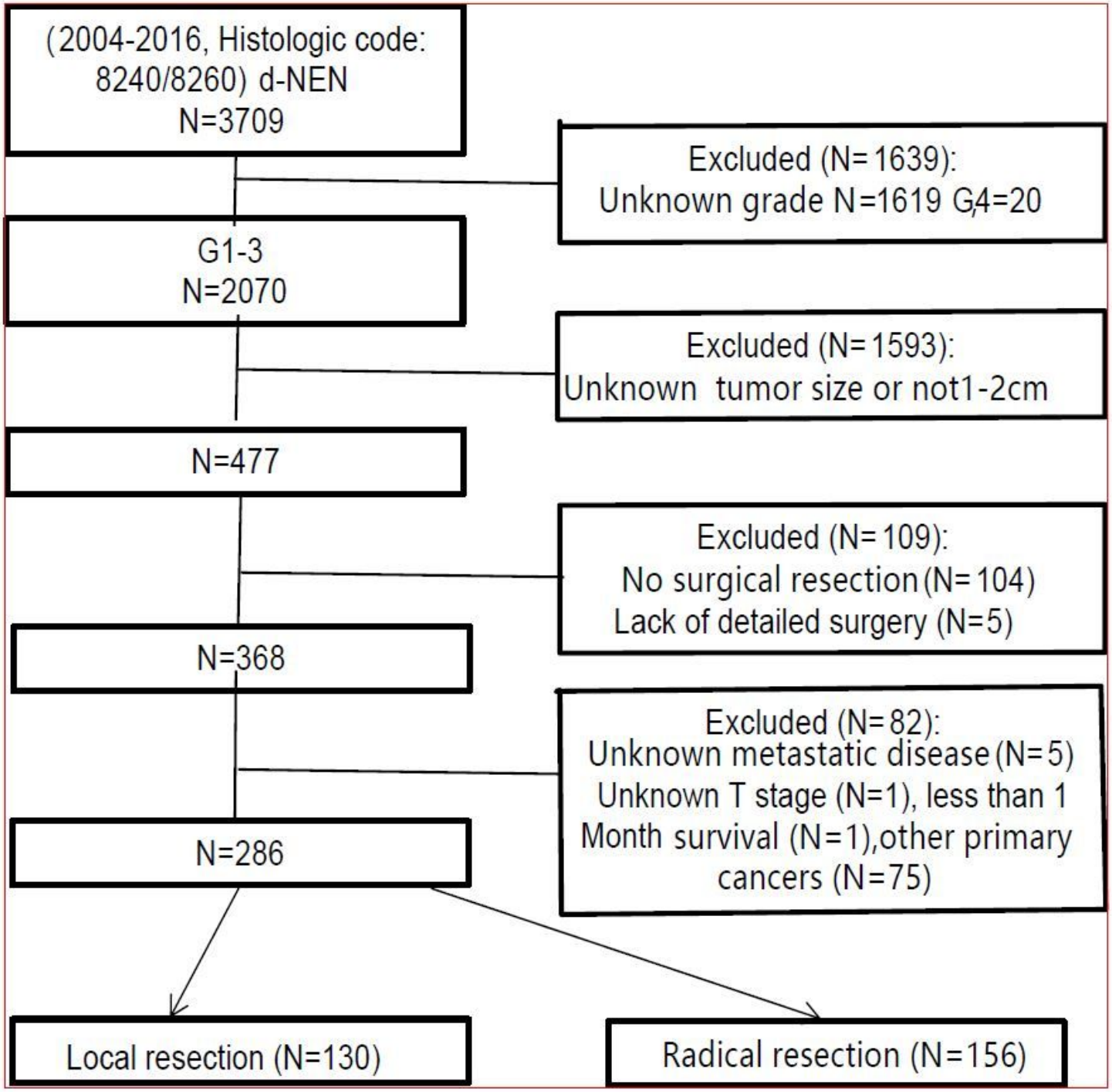

Figure 1

Flow chart of patient cohort selection.

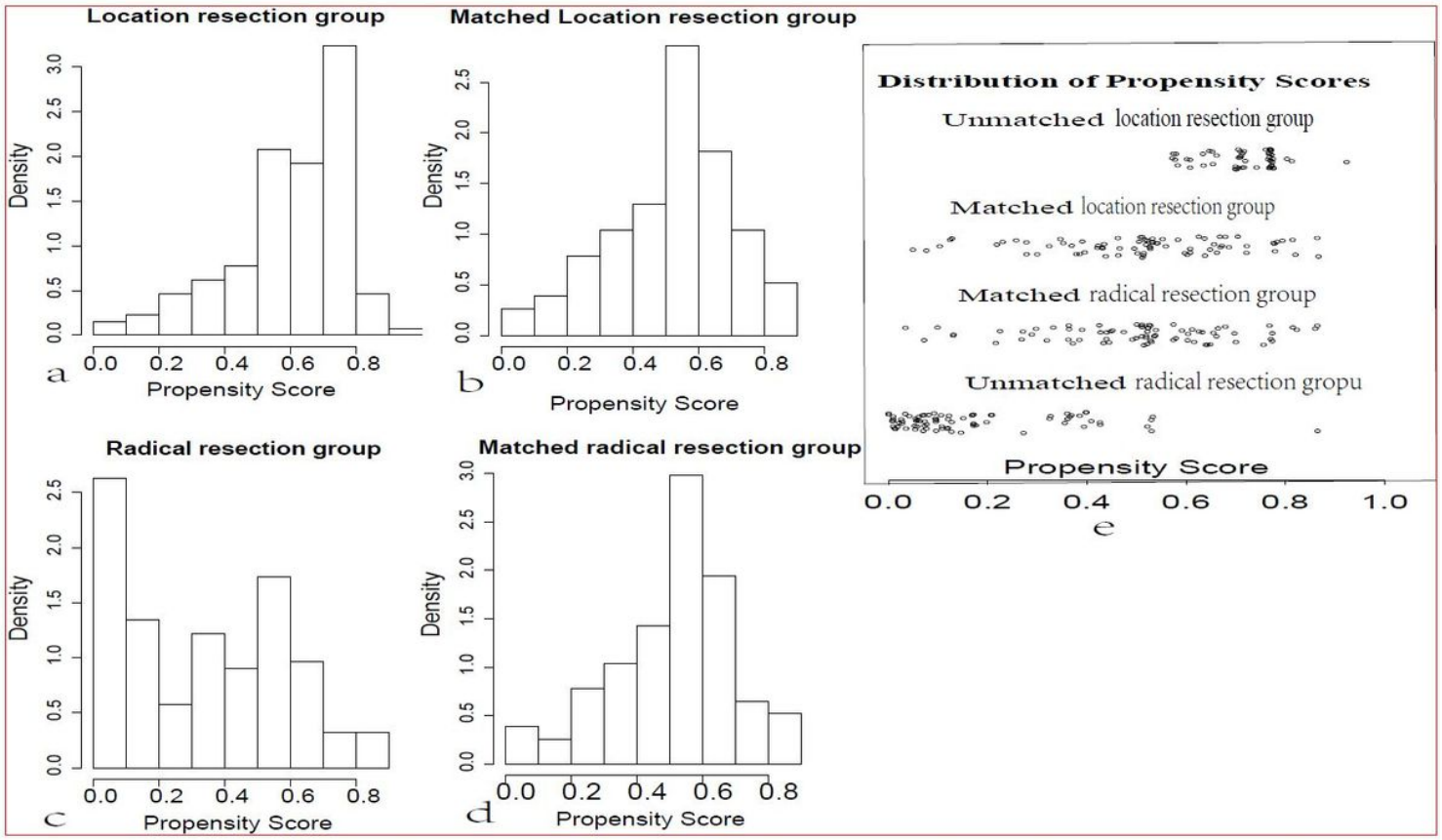

Figure 2

Distribution profiles of the clinicopathologic factors of the patients in the local resection group and radical resection group before and after PSM matching, and distribution profiles of the filter-in and filter-out patients.

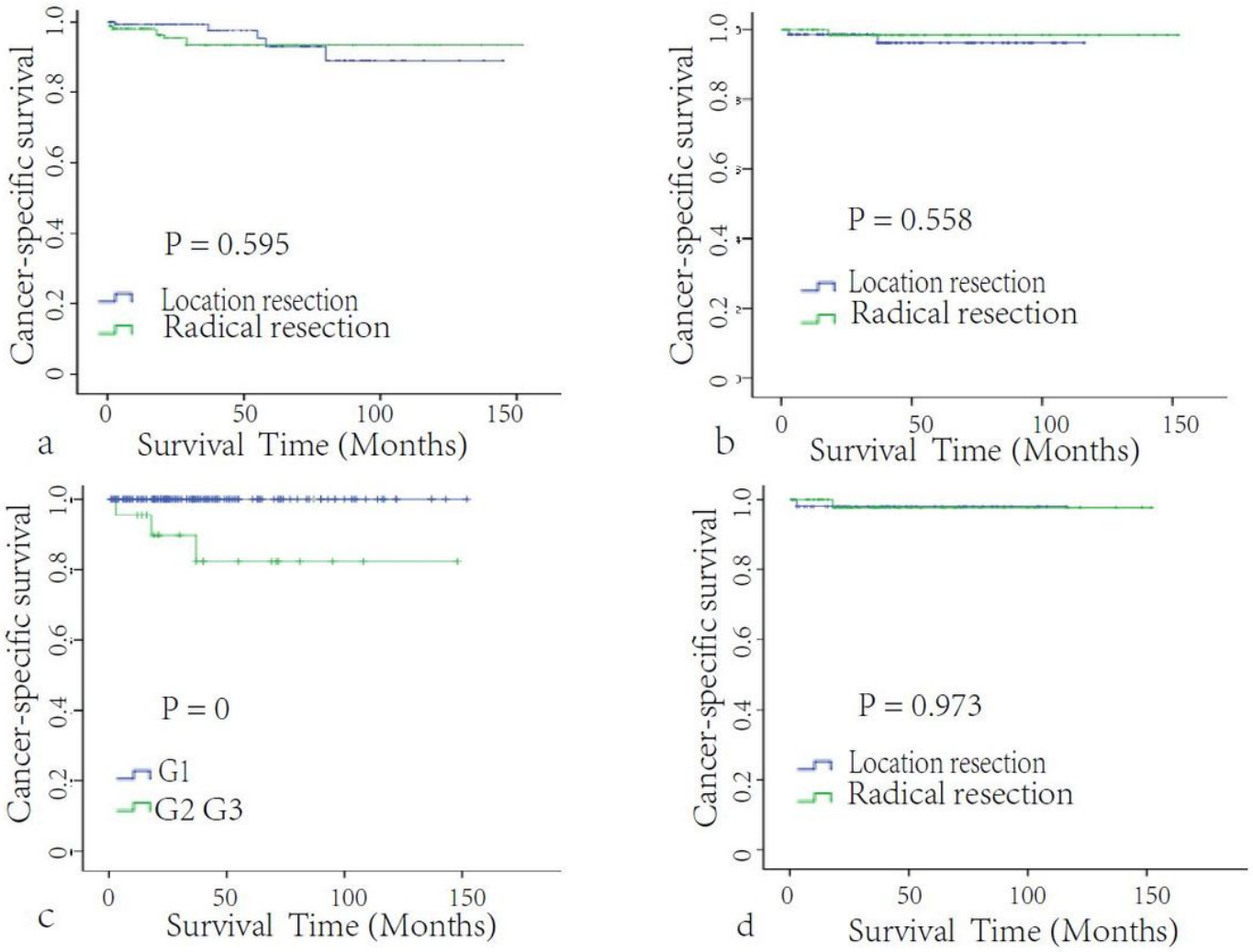

Figure 3

a, Cancer-specific survival of the local resection group and radical resection group before PSM (n=286); b, Cancer-specific survival of the local resection group and radical resection group after PSM (n=154); c, Cancer-specific survival of the different grades. d, Subgroup analysis of the nonmetastatic patients with d-NET stage ≥T2 revealed that a difference in CSS (n=119).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- dataafterPSm.csv
- databeforePSM.xlsx