Pelvic Exenteration Improves Survival in Selected T4bM1 Rectal Cancer Patients: A Multicenter Study

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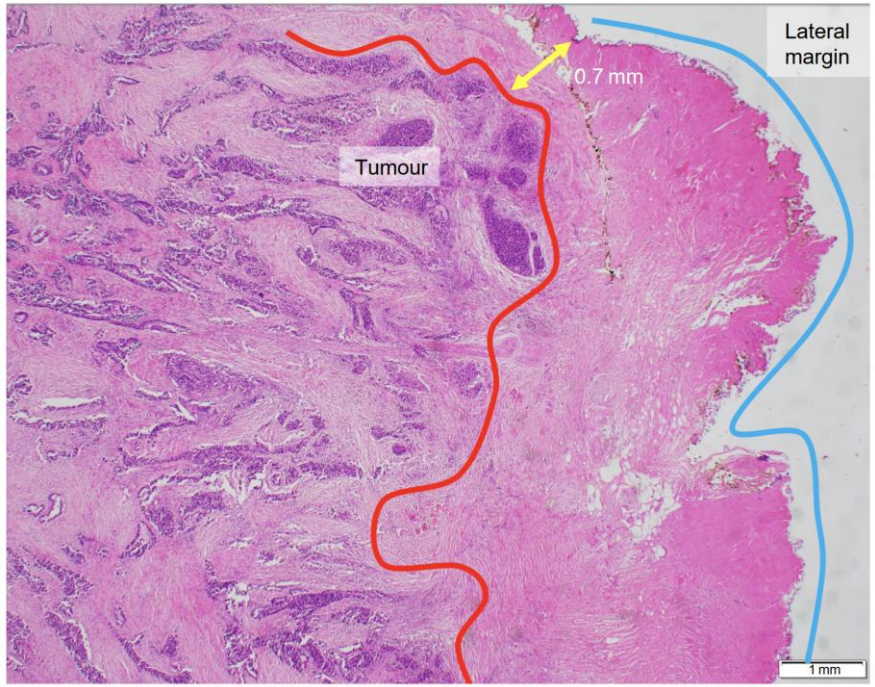
1

INTRODUCTION

Introduction

- Locally advanced rectal cancer (LARC) and locally recurrent rectal cancer (LRRC) with **organ invasion** (*stage T4b and rT4b*) often present with **distant metastases**, challenging radical resection.

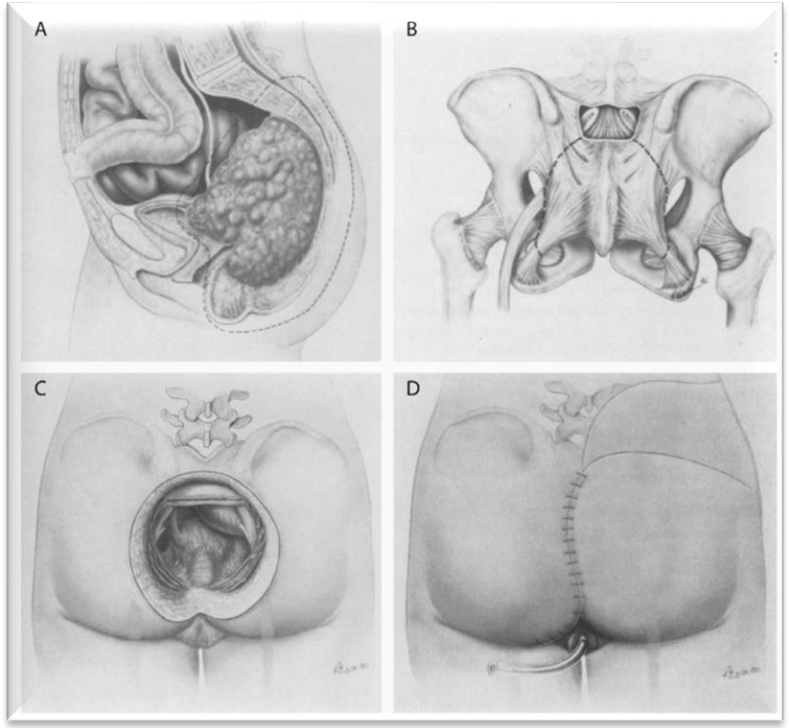
- Large tumors and multi-organ involvement demand high surgical expertise in pelvic exenteration（PE）.



Br J Surg. 2024;111(1):znad450.

PE surgery involves complex pelvic malignancies

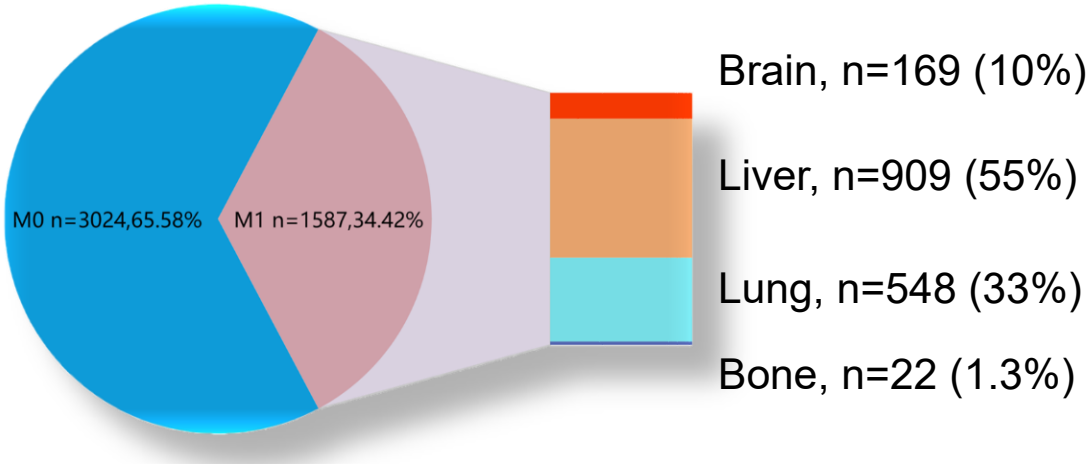
- PE is mainly indicated for pelvic tumors **without distant metastasis**.
- M1 pelvic tumors are contraindications for PE; systemic therapy is preferred.



N Engl J Med. 1950;242(3)
Ann Surg. 1981;194(4):458-471.

International Guidelines: T4bM1？

- Around **1/3 T4b** rectal cancers present with synchronous metastases.
- Guidelines recommend medical therapy for T4bM1 due to poor survival in M1.
- Surgery mainly for symptom relief, not R0 resection.



synchronous metastases in T4b rectal cancer (data from SEER database)

Clinical Observations

- However, some T4bM1/rT4bM1 patients with stable metastases achieved long-term survival after PE.
- Given the strong desire for survival among patients and families, we have selectively performed PE surgery on patients with stable distant metastases.
- We analyzed 617 PE cases from five centers to evaluate outcomes in T4bM1 patients.

2

METHODS

Cohort Establishment

From **January 1, 2007 to September 30, 2024**, PE cohorts included patients with pelvic multi-organ invasive rectal cancer that underwent radical surgery at **five center**:

Hospital name	Representative	PE cases
Peking University Shougang Hospital	**Jin Gu**	196
Wuhan University Zhongnan Hospital	Qun Qian	118
Shanghai Changzheng Hospital	Jian Zhang	112
Hubei Cancer Hospital	Shengwei Ye	97
Peking University Shougang Hospital	Xin Wang	94
		N=617

Inclusion Criteria (Retrospective Study)

Inclusion Criteria

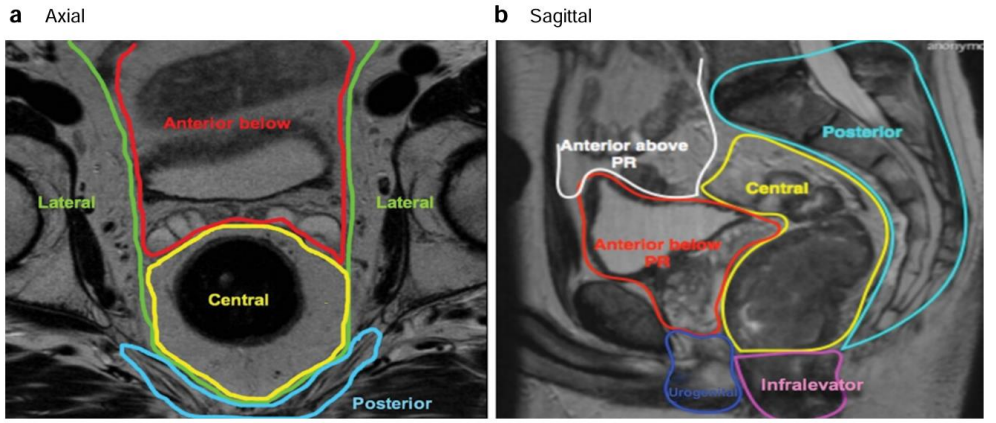
- Preoperative imaging confirming tumor invasion of one or more adjacent pelvic organs;
- Pathologically confirmed primary or recurrent rectal adenocarcinoma;
- Pelvic tumor progression leading to bleeding or infection, making further medical treatment unfeasible;
- MDT consensus that **distant metastases were stable by RECIST standard (no progressive disease for at least three months) and that local R0 resection was feasible;**
- ECOG score ≤3 or ASA score ≤3, with major organ dysfunction but deemed surgically fit after MDT assessment.

Exclusion Criteria

- MDT consensus that metastatic lesions are uncontrollable;
- Patients with multi-organ dysfunction deemed unfit for surgery after MDT assessment;
- Patients with other primary malignancies;
- Patients refusing MDT-recommended preoperative adjuvant therapy; Tumor invasion of the S1 or S2 vertebra.

Treatment Methods

- Patients with distant metastases received **chemotherapy or chemoradiotherapy before surgery**.
- Some patients received FOLFOX/XELOX ± targeted therapy, while others underwent long-course radiotherapy (50.4Gy/25f) ± chemotherapy.
- Preoperative holographic imaging was used to assess surgical approaches *PE Surgery*



PE surgery

- ***Anterior PE*** involving the bladder, urethra, and internal reproductive organs;
- ***Posterior PE*** involving the reproductive organs and rectum, and possibly the anal canal;
- ***Lateral PE***, involving pelvic sidewall structures such as the iliac vessels, piriformis, and obturator internus;
- ***Total PE,*** involving the bladder, urethra, internal reproductive organs, rectum, anus, and associated muscles and ligaments

Data Collection

Study Endpoint

- This retrospective cohort study's primary endpoint was ***OS***, defined as the time from PE surgery to the last follow-up or death from any cause.
- ***Median survival*** was defined as the time at which 50% of the cohort remained alive.

graded according to the Clavien–Dindo classification.12

patients who did not undergo surgery (eMethod 2).

3

RESULTS

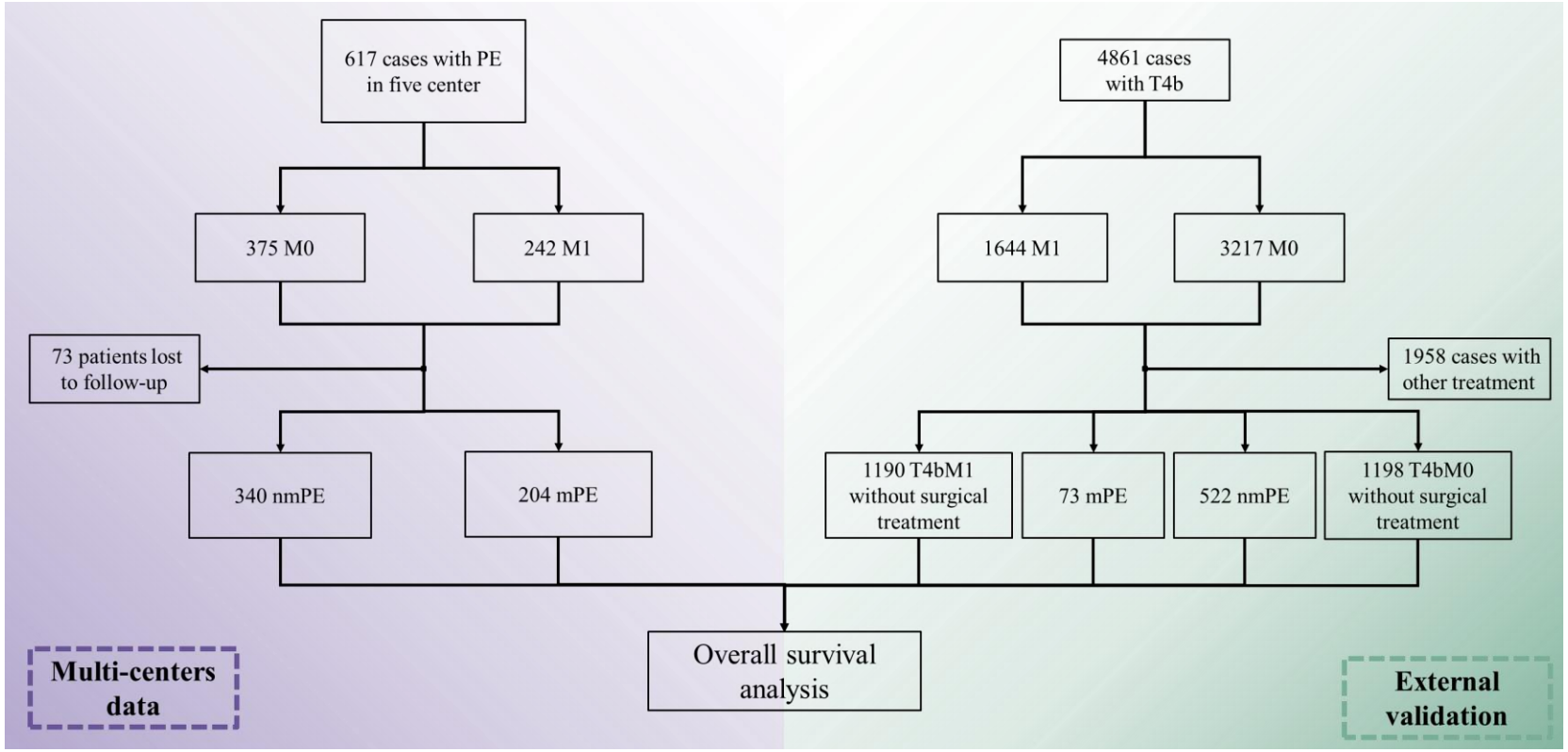
Study Design & Cohorts

- ***PE Cohort***:

617 patients (5 Chinese centers, 2007–2024).

- ***Non-Surgical Groups***:

2,903 patients(SEER database for external validation, 2000–2020).



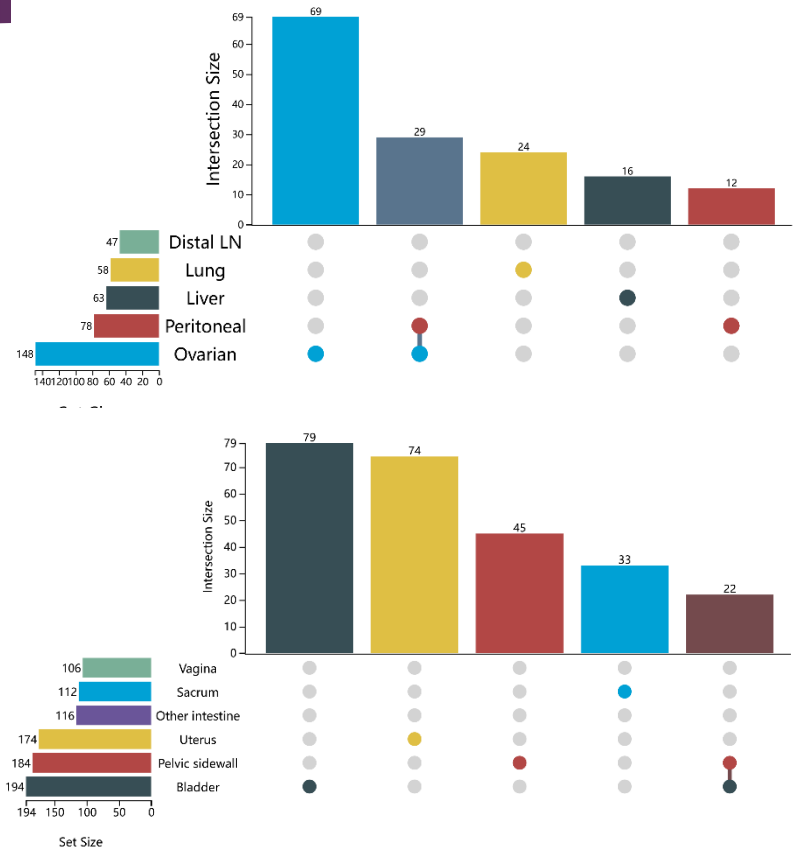
Baseline characteristic

According to AJCC 8th, PE were divided into two groups:

- non-metastasis PE (**nmPE, n=375**)
- metastasis PE(**mPE, n=242**).

The number of M1a, M1b and M1c in mPE group was 133, 31 and 78 respectively.

Liver, lung, parietal peritoneum, ovarian and distal lymph nodes accounted for **26.0%, 24.0%,** 32.2%, 61.2% and 19.4% respectively.

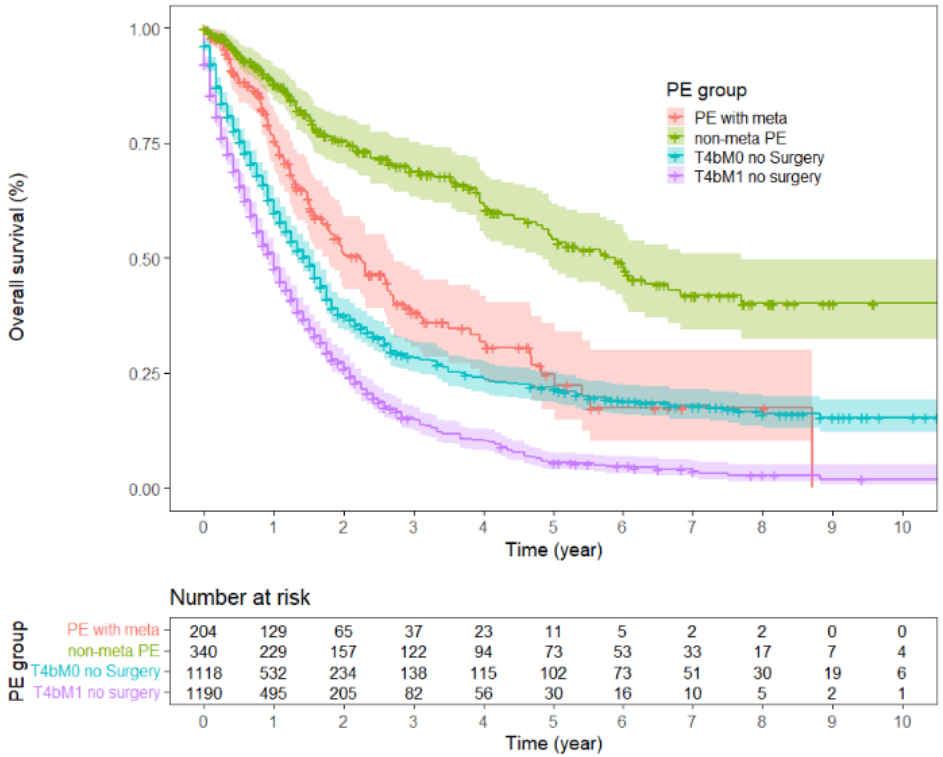


Cohort Disease Burden Distribution

PE significantly improves survival

Compared with T4b rectal cancer without underwent surgery, **PE reduced the risk of death by 65% in T4b patients** (HR=0.35, 95% CI 0.32–0.39, P<.001)

Calculated by PE vs. without surgery



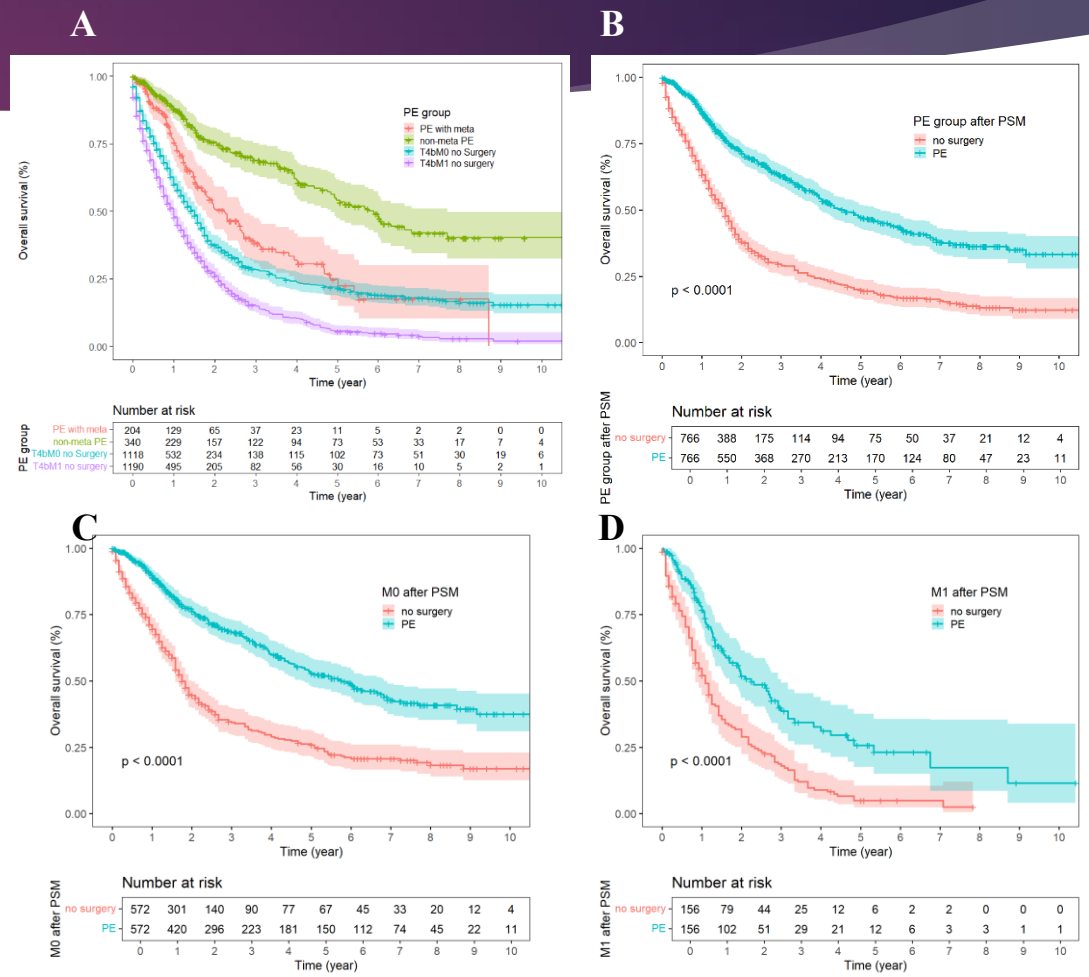
PE significantly improves survival

After propensity score-matched (**PSM**), the **PE population achieved better prognosis**, both in M0 and M1.

Besides:

M1 with PE > non-sur T4bM0

26.8 months vs. 18.0 months

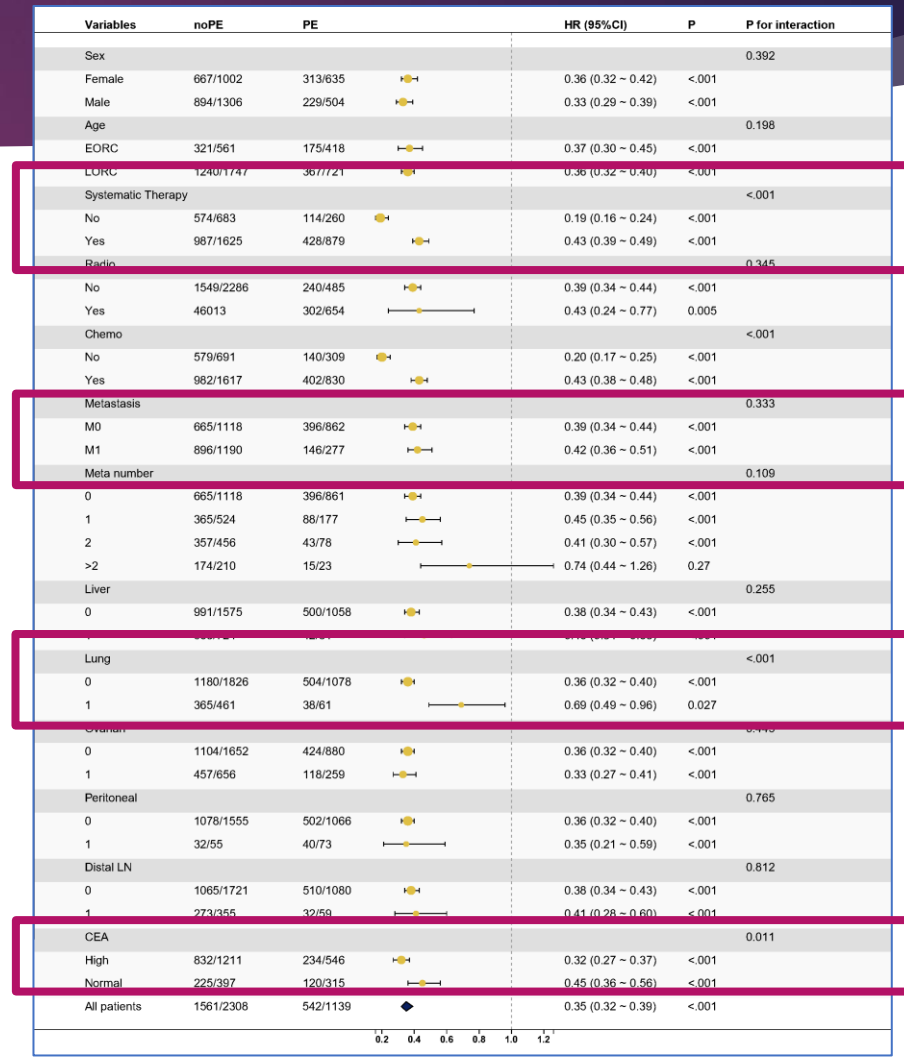


PE for selected patients

Subgroup analysis showed that：these patients are more likely to benefit from PE

- distant metastases<3
- elevated CEA
- Ineligible for systemic therapy

In these cases, comparable survival benefits from PE between M0 and M1 (P=.333).



Variables	noPE	PE	HR (95%CI)	P	P for interaction
Sex					0.392
Female	667/1002	313/635	0.36 (0.32 ~ 0.42)	<.001	
Male	894/1306	229/504	0.33 (0.29 ~ 0.39)	<.001	
Age					0.198
EORC	321/561	175/418	0.37 (0.30 ~ 0.45)	<.001	
LORC	1240/1747	367/721	0.36 (0.32 ~ 0.40)	<.001	
Systematic Therapy					<.001
No	574/683	114/260	0.19 (0.16 ~ 0.24)	<.001	
Yes	987/1625	428/879	0.43 (0.39 ~ 0.49)	<.001	
Radio					0.345
No	1549/2286	240/485	0.39 (0.34 ~ 0.44)	<.001	
Yes	46013	302/654	0.43 (0.24 ~ 0.77)	0.005	
Chemo					<.001
No	579/691	140/309	0.20 (0.17 ~ 0.25)	<.001	
Yes	982/1617	402/830	0.43 (0.38 ~ 0.48)	<.001	
Metastasis					0.333
M0	665/1118	396/862	0.39 (0.34 ~ 0.44)	<.001	
M1	896/1190	146/277	0.42 (0.36 ~ 0.51)	<.001	
Meta number					0.109
0	665/1118	396/861	0.39 (0.34 ~ 0.44)	<.001	
1	365/524	88/177	0.45 (0.35 ~ 0.56)	<.001	
2	357/456	43/78	0.41 (0.30 ~ 0.57)	<.001	
>2	174/210	15/23	0.74 (0.44 ~ 1.26)	0.27	
Liver					0.255
0	991/1575	500/1058	0.38 (0.34 ~ 0.43)	<.001	
Lung					<.001
0	1180/1826	504/1078	0.36 (0.32 ~ 0.40)	<.001	
1	365/461	38/61	0.69 (0.49 ~ 0.96)	0.027	
Ovarian					0.445
0	1104/1652	424/880	0.36 (0.32 ~ 0.40)	<.001	
1	457/656	118/259	0.33 (0.27 ~ 0.41)	<.001	
Peritoneal					0.765
0	1078/1555	502/1066	0.36 (0.32 ~ 0.40)	<.001	
1	32/55	40/73	0.35 (0.21 ~ 0.59)	<.001	
Distal LN					0.812
0	1065/1721	510/1080	0.38 (0.34 ~ 0.43)	<.001	
1	273/355	32/59	0.41 (0.28 ~ 0.60)	<.001	
CEA					0.011
High	832/1211	234/546	0.32 (0.27 ~ 0.37)	<.001	
Normal	225/397	120/315	0.45 (0.36 ~ 0.56)	<.001	
All patients	1561/2308	542/1139	0.35 (0.32 ~ 0.39)	<.001	

0.2 0.4 0.6 0.8 1.0 1.2

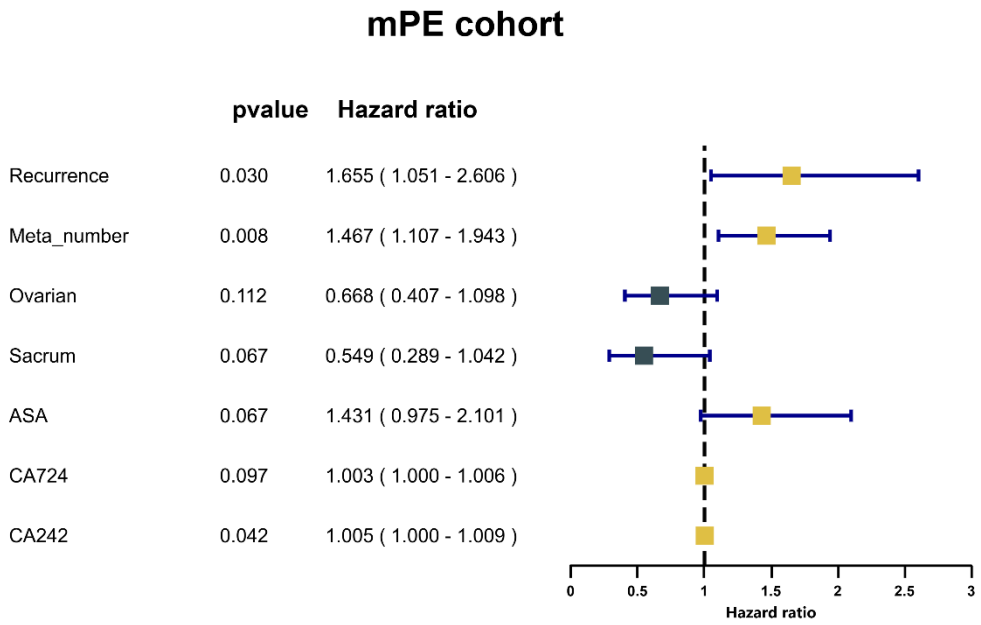
Which M1 suitable for PE?

Cox analysis in the M1 patients, We identified three high-risk factors:

- Recurrent rectal cancer (HR=1.65, P=0.03)
- elevated preoperative CA242 (HR=1.005, P=0.04)
- more than three metastatic organs (HR=1.47, P=0.007)

Then mPE were separated into two subgroup:

- **high risk, HR-mPE**（n=128）
- **Low risk, LR-mPE**（n=76）



Risk Score = 0.382939 (Number of Metastases) + 0.004811(CA242) + 0.503694(Recurrent PE). cutoff score=0.7899

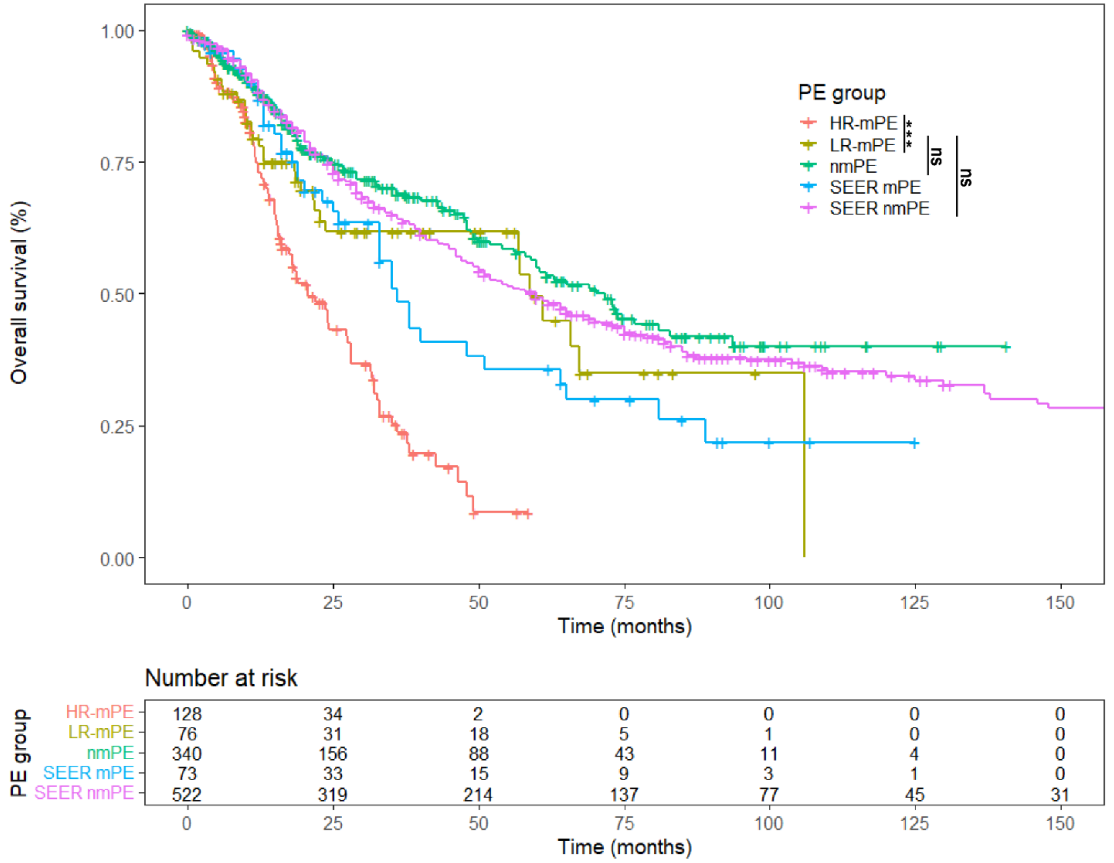
Subgroup prognosis for mPE

Prognosis in low risk group(LR-mPE)：

- LR-mPE < nmPE（**P=0.09**）
  58.8m vs. 70.8m

- LR-mPE < SEER-nmPE（**P=0.215**）
  58.8m vs. 60.0m

The OS of LR-mPE is not significantly different from that of M0 with PE in our five centers, and also, better than that in SEER database.



The reported PE pr

Reviewing the **relevant literature** on the **M0** LARC/LRRC after PE

- 3-year OS : 8.1%-76.3%
- 5-year OS : 3%-69%.

Although with synchronous metastases, the LR-mPE:

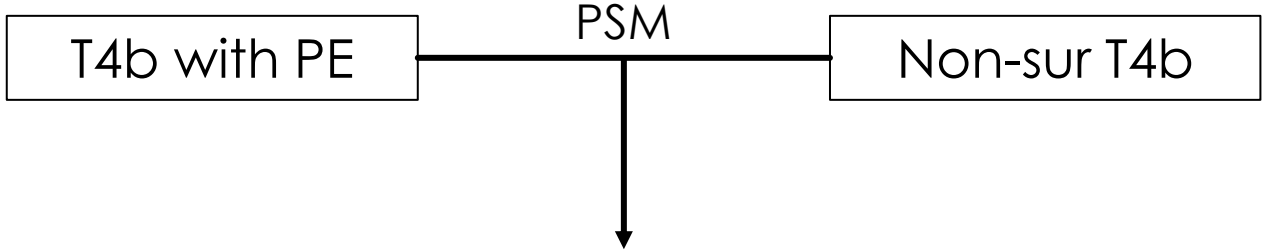
- 3-year OS: 58%
- 5-year OS: 45%

The prognosis of low-risk M1 patients was acceptable.

Author	year	Number	Population	1-year OS	2-year OS	3-year OS	5-year OS
Charlotte Ralston[13]	2024	120	Single center for LARC/LRRC	91%	78%		
Mufaddal Kazi[14]	2024	275	Single center for LARC		LPE: 87.9% RPE: 92.6%		
M Zhuang[15]	2023	105	Single center for LARC/LRRC			LPE：76.3% OPE：64.4%	
Catalina A. Palma[16]	2023	329	Single center for LARC/LRRC	PC: 90.8% RC: 88.7%		PC: 68.1% RC: 62.2%	PC: 58.6% RC: 49.5%
Daniel Steffens[17]	2023	981	Single center for LARC/LRRC	LARC: 90.1% LRRC: 90.9%	LARC: 79.7% LRRC: 76.6%		LARC: 66.3% LRRC: 44.6%
Mufaddal Kazi[18]	2023	285	Single center for RC			60.5%	
Yeqian Huang[19]	2022	271	Single center for LARC/LRRC				LARC: 59.0%. LRRC: 42.4%
J. Tang[20]	2022	96	Single center for LARC		OPE：77.2% LPE：77.8%	OPE:70.9% LPE:75.7%	
Toshisada Aiba[21]	2022	73	Single center for LARC/LRRC				Narrow RM:13.5%. Wide RM:69%. Exposed RM: 28.1%.
Jan M. van Rees[22]	2021	227	Single center for LARC/LRRC				Low SMD:37%. High SMD: 53%
M Kazi[23]	2021	158	Single center for LARC			LPE: 79.4% OPE: 60.2%	
Mufaddal Kazi[24]	2021	100	Single center for LARC			With urinary complication: 43.5% Without urinary complication: 62.7%	
PelvEx Collaborative[25]	2018	1184	Multi-center for LRRC			R0: 48.1% R1: 33.9% R2: 15%	R0: 28.2% R1: 17.3% R2: 3%
PelvEx Collaborative[4]	2019	1291	Multi-center for LARC			R0: 56.4% R1: 29.6% R2: 8.1%	R0: 37.8% R1: 12.3% R2:<8.1%
Range				**88.7%-91%**	**76.6%-92.6%**	**8.1%-76.3%**	**3%-69%**

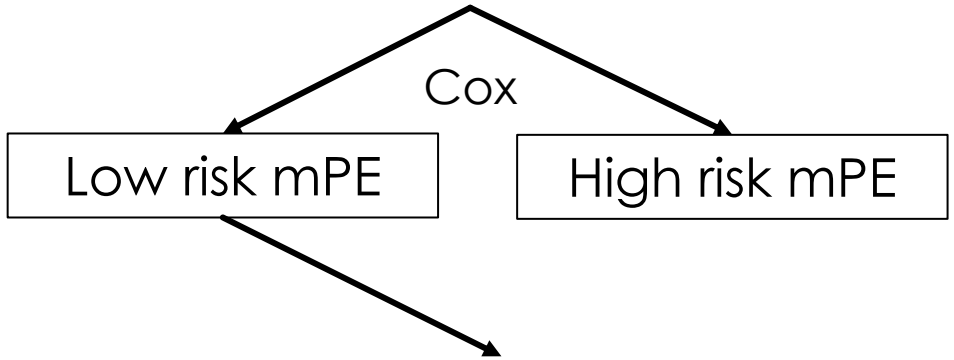
Result

Total cohort



- PE reduced 65% death risk
- T4bM1 with PE > T4bM0 without surgery
- Comparable survival benefits between M0 and M1

M1 cohort



Overall survival:

- LR-mPE ≈ nmPE
- LR-mPE ≈ SEER-nmPE
- LR-mPE ≈ reported PE in M0

PE improved survival in both M0 and M1 patients, with the greatest benefit in selected M1 cases with stable disease.

4

CONCLUSION

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- **For selected patients—PE surgery provides clear benefits.**
- **M1 should not be an contraindication for PE treatment, especially in low-risk patients.**

Thank you for your listening!