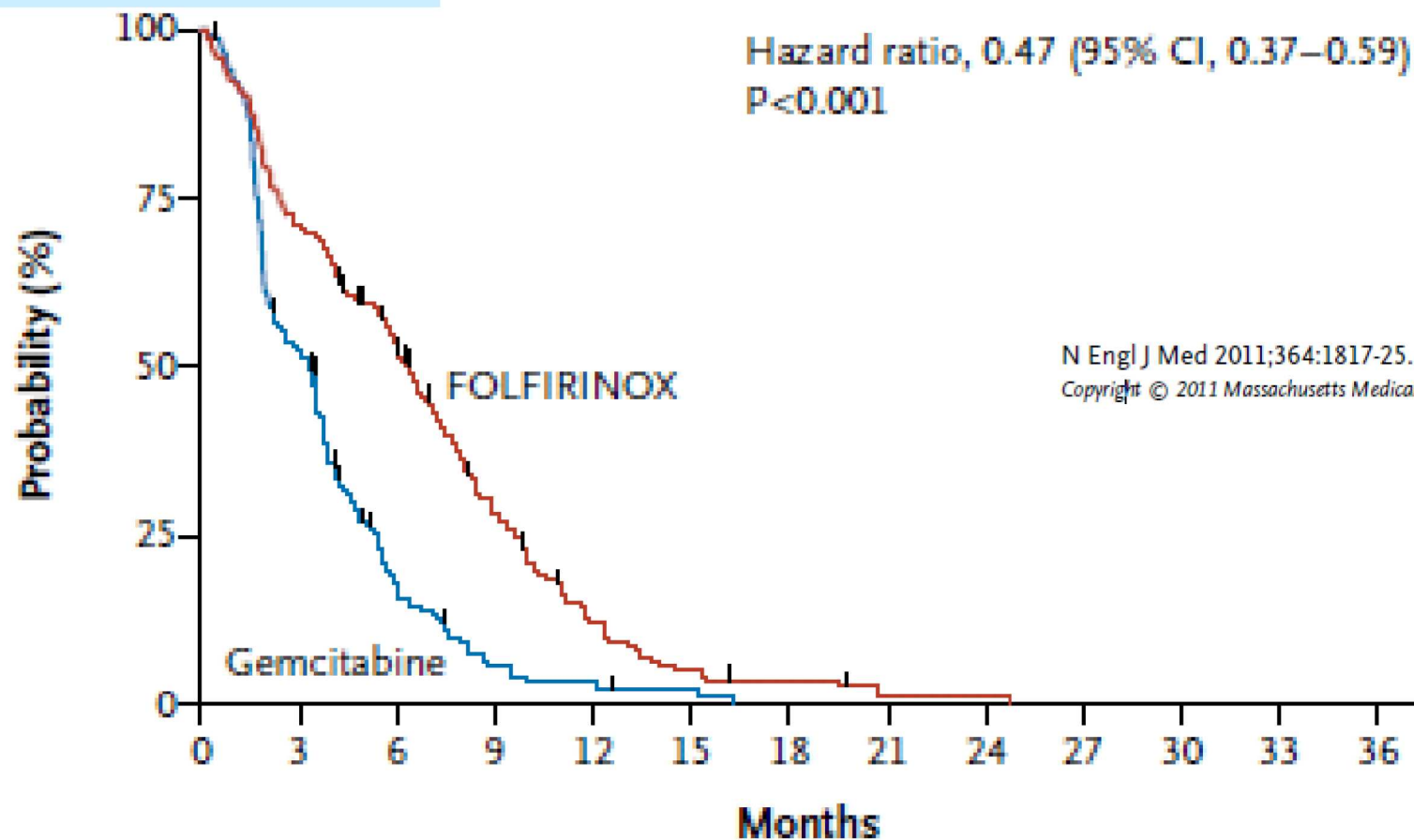


Figure 1. Kaplan–Meier Estimates of Overall Survival and Progression-free Survival, According to Treatment Group.

B Progression-free Survival



No. at Risk

Gemcitabine	171	88	26	8	5	2	0	0	0	0	0	0	0
FOLFIRINOX	171	121	85	42	17	7	4	1	1	0	0	0	0

奏效率

Table 2. Objective Responses in the Intention-to-Treat Population.*

Variable	FOLFIRINOX (N= 171)	Gemcitabine (N= 171)	P Value
Response — no. (%)			
Complete response	1 (0.6)	0	
Partial response	53 (31.0)	16 (9.4)	
Stable disease	66 (38.6)	71 (41.5)	
Progressive disease	26 (15.2)	59 (34.5)	
Could not be evaluated	25 (14.6)	25 (14.6)	
Rate of objective response†			<0.001
No. (%)	54 (31.6)	16 (9.4)	
95% CI	24.7–39.1	5.4–14.7	
Rate of disease control‡			<0.001
No. (%)	120 (70.2)	87 (50.9)	
95% CI	62.7–76.9	43.1–58.6	
Response duration — mo			0.57
Median	5.9	3.9	
95% CI	4.9–7.1	3.1–7.1	

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FOLFIRINOX は発熱性好中球減少症をきたしやすい

Table 3. Most Common Grade 3 or 4 Adverse Events Occurring in More Than 5% of Patients in the Safety Population.*

Event	FOLFIRINOX (N= 171) <i>no. of patients/total no. (%)</i>	Gemcitabine (N= 171)	P Value
Hematologic			
Neutropenia	75/164 (45.7)	35/167 (21.0)	<0.001
Febrile neutropenia	9/166 (5.4)	2/169 (1.2)	0.03
Thrombocytopenia	15/165 (9.1)	6/168 (3.6)	0.04
Anemia	13/166 (7.8)	10/168 (6.0)	NS
Nonhematologic			
Fatigue	39/165 (23.6)	30/169 (17.8)	NS
Vomiting	24/166 (14.5)	14/169 (8.3)	NS
Diarrhea	21/165 (12.7)	3/169 (1.8)	<0.001
Sensory neuropathy	15/166 (9.0)	0/169	<0.001
Elevated level of alanine aminotransferase	12/165 (7.3)	35/168 (20.8)	<0.001
Thromboembolism	11/166 (6.6)	7/169 (4.1)	NS

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* Events listed are those that occurred in more than 5% of patients in the safety population. NS denotes not significant. Copyright © 2011 Massachusetts Medical Society.

結 論

- FOLFIRINOXはGEMと比較して毒性は強いものの有意に生存期間の延長を認めた。
- PS良好な転移性膵癌の患者に対する化学療法の1st-lineになりうる。

Systemic Therapy for Locally Advanced and Metastatic Pancreatic Adenocarcinoma

切除不能癌に対するランダム化比較試験

(分子標的薬を除く)

GEM単剤療法

<1> 他の薬剤(単剤)

<2> GEMを含む併用療法

<3> GEMを含まない併用療法
(FOLFIRINOXなど)