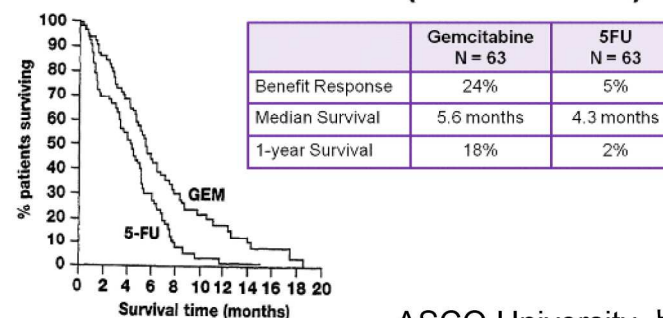


<1> GEM単剤療法と他の薬剤(単剤)とのランダム化比較試験

| 報告者 報告年 | 治療法 | 患者数 | 生存期間中央値 (月) | P値 |
|-------------------|------------------|-----|----------------|--------|
| Burris 1997 | GEM | 63 | 5.7 | |
| | 5-FU | 63 | 4.4 | < 0.01 |
| Bramhall 2001 | GEM | 103 | 5.6 | |
| | marimastat 5mg | 104 | 3.7 | 0.163 |
| | marimastat 10mg | 105 | 3.5 | 0.045 |
| | marimastat 25mg | 102 | 4.2 | 0.78 |
| Gansauge 2002 | GEM | 30 | 5.2 | |
| | NSC-631570 | 30 | 7.9 | < 0.01 |
| | GEM + NSC-631570 | 30 | 10.4 | < 0.01 |
| Moore 2003 | GEM | 139 | 6.6 | |
| | BAY12-9566 | 138 | 3.7 | < 0.01 |
| Cheverton 2004 | GEM | 170 | 6.6 | |
| | exatecan | 169 | 5 | 0.09 |

5-FU : 5-fluorouracil, GEM : gemcitabine

**Best Survival Curve in APC
Gemcitabine vs. 5FU (until 2010....)**



ASCO University より

(膵癌診療ガイドライン2009)

<2> GEM単剤療法とGEMを含む併用療法とのランダム化比較試験ーその1

| 報告者 報告年 | 治療法 | 患者数 | 生存期間中央値 (月) | P値 |
|--------------------|-----------------------|-----|----------------|------|
| Berlin 2002 | GEM | 162 | 5.4 | 0.09 |
| | GEM + 5-FU | 160 | 6.7 | |
| Riess 2005 | GEM | 236 | 6.2 | 0.68 |
| | GEM + 5-FU + FA | 230 | 5.9 | |
| Herrmann 2005 | GEM | 159 | 8.4 | 0.31 |
| | GEM + capecitabine | 160 | 7.3 | |
| Cunningham 2005 | GEM | 266 | 6 | 0.03 |
| | GEM + capecitabine | 267 | 7.4 | |
| Oettle 2005 | GEM | 282 | 6.3 | 0.85 |
| | GEM + pemetrexed | 283 | 6.2 | |
| Colucci 2002 | GEM | 54 | 20週 | 0.48 |
| | GEM + cisplatin | 53 | 30週 | |
| Heinemann 2006 | GEM | 97 | 6 | 0.15 |
| | GEM + cisplatin | 98 | 7.5 | |

| 報告者 報告年 | 治療法 | 患者数 | 生存期間中央値 (月) | P値 |
|----------------------|--------------------------|-----|----------------|------|
| Louvet 2005 | GEM | 156 | 7.1 | 0.13 |
| | FDR-GEM + oxaliplatin | 157 | 9 | |
| Poplin 2006 | GEM | 279 | 4.9 | 0.05 |
| | FDR-GEM | 277 | 6 | |
| | FDR-GEM + oxaliplatin | 276 | 5.9 | |
| Rocha Lima 2004 | GEM | 180 | 6.6 | 0.79 |
| | GEM + irinotecan | 180 | 6.3 | |
| Stathopoulos 2006 | GEM | 70 | 6.5 | 0.97 |
| | GEM + irinotecan | 60 | 6.4 | |
| Abou-Alfa 2006 | GEM | 174 | 6.2 | 0.52 |
| | GEM + exatecan | 175 | 6.7 | |
| Bramhall 2002 | GEM | 119 | 164日 | 0.95 |
| | GEM + marimastat | 120 | 165.5日 | |

(膵癌診療ガイドライン2009)

とりわけ、

Gemcitabine vs. Gemcitabine + S-1 (ASCO 2011)

| | MST | | |
|--|-------|---------|---------|
| | GEM | GEM+S-1 | |
| Randomized phase III study of gemcitabine plus S-1 (GS) versus S-1 versus gemcitabine (GEM) in unresectable advanced pancreatic cancer (PC) in Japan and Taiwan: GEST study. | 8.8 M | 10.1 M | p=0.150 |
| The final analysis of a multicenter randomized controlled trial of gemcitabine (G) alone versus gemcitabine and S-1 combination therapy (GS) in patients with unresectable advanced pancreatic cancer (PC): GEMSAP study. | 8.8M | 13.5M | p=0.104 |
| A randomized phase II study of gemcitabine plus S-1 versus gemcitabine alone in patients with unresectable pancreatic cancer. | 7.9M | 13.0M | p=0.04 |

**Targeted Therapy in
Pancreatic Adenocarcinoma:
Is There a Role?**

GEM単剤療法とGEMを含む併用療法とのランダム化比較試験 —その2

| | | | | |
|--------------------|----------------------|-----|------|------|
| Van Cutsem 2004 | GEM | 347 | 182日 | 0.75 |
| | GEM + tipifarnib | 341 | 193日 | |
| Moore 2005 | GEM | 284 | 5.91 | 0.04 |
| | GEM + erlotinib | 285 | 6.24 | |
| Kindler 2007 | GEM | 300 | 6.1 | 0.78 |
| | GEM + bevacizumab | 302 | 5.8 | |
| Philip 2007 | GEM | 369 | 5.9 | 0.14 |
| | GEM + cetuximab | 366 | 6.4 | |

(膵癌診療ガイドライン2009)

Phase III Anti-Vascular Trials in PC Four Negative Trials...

| Drug | N | RR | Med OS | Reference |
|--|-----|-------|------------|------------------------|
| Gemcitabine + Bevacizumab | 590 | 13% | 5.8 months | Kindler CALGB 80303 |
| Gemcitabine + Placebo | | 10% | 6.1 months | |
| Gemcitabine + Erlotinib + Bevaciz | 607 | 13.5% | 7.1 months | Van Cutsem AVITA |
| Gemcitabine + Erlotinib | | 8.6% | 6 months | |
| Gemcitabine + Axitinib | 593 | NR | 8.5 months | Kindler |
| Gemcitabine + Placebo | | NR | 8.3 months | |
| Gemcitabine + Aflibercept (VEGF-Trap) | 594 | NR | 7.7 months | Rougier |
| Gemcitabine + Placebo | | NR | 6.5 months | |

VEGFR1 and VEGFR2,
fused to an Fc segment of IgG1

VEGF-R1,2,3 inhibitor