

# Nouveautés du cancer du pancréas 2018

Quoi de neuf en Hépatogastro  
12 septembre 2018

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# Incidence en augmentation

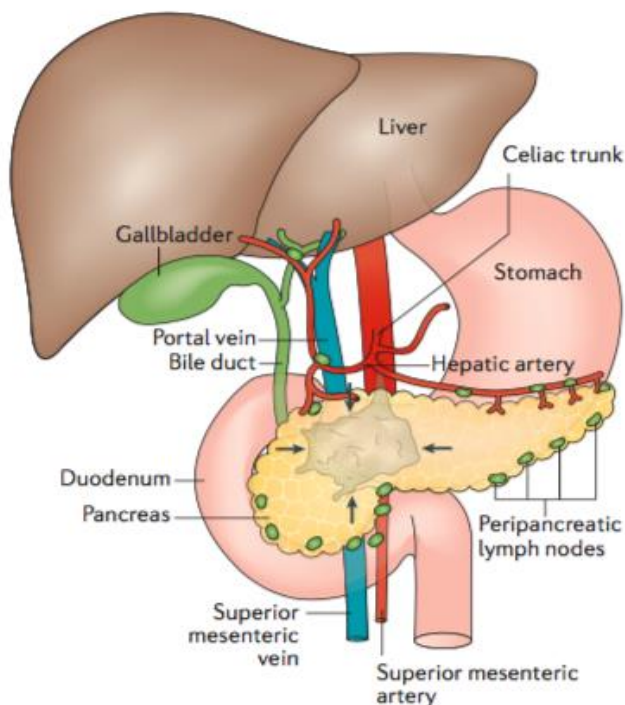
|                  | 1982 | 1992 | 1997 | 2002 | 2007 | 2012 | Mean annual percent change (APC) |
|------------------|------|------|------|------|------|------|----------------------------------|
| <b>Incidence</b> |      |      |      |      |      |      |                                  |
| Men              | 4.8  | 6.3  | 7.1  | 7.9  | 8.8  | 9.6  | 2.3% (2.1–2.6)                   |
| Women            | 2.3  | 3.4  | 4.1  | 4.8  | 5.7  | 6.8  | 3.6% (3.3–3.9)                   |
| <b>Mortality</b> |      |      |      |      |      |      |                                  |
| Men              | 8.2  | 8.1  | 8.1  | 8.2  | 8.1  | 8.1  | 0% (–0.3–0.2)                    |
| Women            | 4.0  | 4.4  | 4.6  | 4.8  | 5.1  | 5.4  | 1% (0.7–1.3)                     |

<sup>a</sup>Per 100 000.

# Bilan d'extension et résécabilité

|                  | 1982 | 1992 | 1997 | 2002 | 2007 | 2012 | Mean annual percent change (APC) |
|------------------|------|------|------|------|------|------|----------------------------------|
| <b>Incidence</b> |      |      |      |      |      |      |                                  |
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<sup>a</sup>Per 100 000.



**Tableau 3. Classification des tumeurs du pancréas à l'issue du bilan morphologique, selon le National Comprehensive Cancer Network (NCCN) (*Pancreatic adenocarcinoma practice guidelines in oncology*. Fort Washington, PA, 2009 ; [http://www.nccn.org/professionals/physician\\_gls/PDF/pancreatic.pdf](http://www.nccn.org/professionals/physician_gls/PDF/pancreatic.pdf)).**

## Résécable

Pas de métastase à distance  
 Persistance d'un liseré graisseux autour du TC et de l'AMS  
 VMS, VP libres

## Borderline

AMS < 180°  
 Atteinte artère hépatique si réparable  
 Atteinte unilatérale ou bilatérale VMS/VP (> 180°)  
 Thrombose VMS, courte réparable

## Non résécable

Métastases à distance  
 Atteinte AMS > 180° et /ou atteinte TC  
 Atteinte aortique  
 Thrombose VMS/VP non réparable

TC : tronc cœliaque ; AMS : artère mésentérique supérieure ;  
 VMS : veine mésentérique supérieure ; VP : veine porte.

# Un pronostic qui reste sombre

|                  | 1982 | 1992 | 1997 | 2002 | 2007 | 2012 | Mean annual percent change (APC) |
|------------------|------|------|------|------|------|------|----------------------------------|
| <b>Incidence</b> |      |      |      |      |      |      |                                  |
| Men              | 4.8  | 6.3  | 7.1  | 7.9  | 8.8  | 9.6  | 2.3% (2.1–2.6)                   |
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| <b>Mortality</b> |      |      |      |      |      |      |                                  |
| Men              | 8.2  | 8.1  | 8.1  | 8.2  | 8.1  | 8.1  | 0% (–0.3–0.2)                    |
| Women            | 4.0  | 4.4  | 4.6  | 4.8  | 5.1  | 5.4  | 1% (0.7–1.3)                     |

<sup>a</sup>Per 100 000.

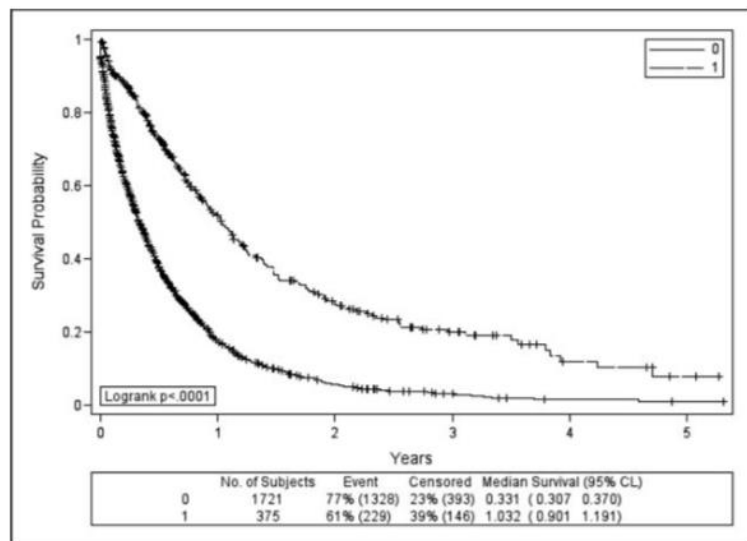
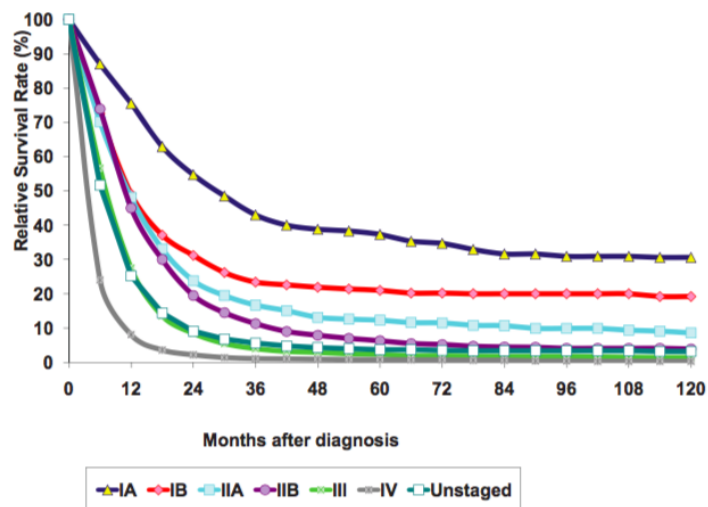


Fig. 3. Overall survival for patients diagnosed with pancreatic cancer in Alabama 1996 to 2000 stratified by surgical treatment (yes = 1, no = 0).

Figure 7.2: Carcinomas of the Exocrine Pancreas: Relative Survival Rates (%) by AJCC Stage, 6th Edition, Ages 20+, 12 SEER Areas, 1988-2001



# Récidive quasi constante si chirurgie seule

**Table 2.** Demographics and patterns of recurrence for 26 autopsied patients

| Patient no. | UICC Stage      |    |    |    |      | Pathology of resected specimens |    |    |    | Survival time (mo) | Cause of death        | Pattern of recurrence |   |   |    |   | Sites of distant metastasis not including H, P, or LN |
|-------------|-----------------|----|----|----|------|---------------------------------|----|----|----|--------------------|-----------------------|-----------------------|---|---|----|---|-------------------------------------------------------|
|             | Surgical margin | pT | pN | pM | pTNM | Histological type               | RP | PL | PV |                    |                       | L                     | H | P | LN | M |                                                       |
| 1           | —               | 3  | 0  | 0  | IIA  | tub2                            | —  | —  | —  | 5                  | Liver abscess         | •                     | • | — | —  | • | Lung                                                  |
| 2           | —               | 3  | 0  | 0  | IIA  | tub2                            | +  | +  | +  | 15                 | DOC                   | •                     | • | • | •  | • | Mesenteric lymph nodes                                |
| 3           | +               | 3  | 0  | 0  | IIA  | tub2                            | +  | +  |    | 19                 | DOC                   | •                     | • | • | •  | • | Lung, heart, adrenal                                  |
| 4           | —               | 3  | 1  |    |      |                                 |    |    |    |                    |                       |                       |   |   |    |   | Lung, heart, kidney, skin, thyroid, testis            |
| 5           | —               | 3  | 1  |    |      |                                 |    |    |    |                    |                       |                       |   |   |    |   | Bone, bronchus, adrenal, perigastric lymph nodes      |
| 6           | —               | 3  | 1  |    |      |                                 |    |    |    |                    |                       |                       |   |   |    |   | Pleura, perigastric lymph nodes                       |
| 7           | —               | 3  | 1  |    |      |                                 |    |    |    |                    |                       |                       |   |   |    |   | Lung                                                  |
| 8           | —               | 4  | 1  |    |      |                                 |    |    |    |                    |                       |                       |   |   |    |   | Lung, pleura                                          |
| 9           | +               | 4  | 0  |    |      |                                 |    |    |    |                    |                       |                       |   |   |    |   | Pleura                                                |
| 10          | —               | 3  | 1  |    |      |                                 |    |    |    |                    |                       |                       |   |   |    |   | Abdominal wall, bone                                  |
| 11          | —               | 3  | 0  |    |      |                                 |    |    |    |                    |                       |                       |   |   |    |   | Perigastric lymph nodes                               |
| 12          | —               | 3  | 0  |    |      |                                 |    |    |    |                    |                       |                       |   |   |    |   |                                                       |
| 13          | —               | 3  | 0  |    |      |                                 |    |    |    |                    |                       |                       |   |   |    |   |                                                       |
| 14          | —               | 3  | 1  |    |      |                                 |    |    |    |                    |                       |                       |   |   |    |   | Lung, stomach, adrenal, perigastric lymph nodes       |
| 15          | —               | 3  | 1  | 0  | IIB  | tub2                            | +  | —  | +  | 17                 | DOC                   | •                     | • | — | —  | — |                                                       |
| 16          | —               | 3  | 1  | 0  | IIB  | tub2                            | +  | —  | +  | 41                 | DOC                   | •                     | • | • | —  | • | Lung, pleura, mesenteric lymph nodes                  |
| 17          | —               | 3  | 1  | 0  | IIB  | tub2                            | +  | +  | —  | 19                 | DOC                   | •                     | • | — | •  | • | Adrenal, bone marrow                                  |
| 18          | —               | 3  | 1  | 1  | IV   | tub2                            | +  | +  |    | 33                 | DOC (local)           | •                     | • | — | —  | • | Lung                                                  |
| 19          | —               | 3  | 0  | 0  | IIA  | tub2                            | +  | —  | +  | 16                 | Myocardial infarction | —                     | — | — | —  | • | Lung                                                  |
| 20          | —               | 3  | 1  | 0  | IIB  | tub2                            | +  | +  |    | 17                 | DOC                   | —                     | — | • | —  | — |                                                       |
| 21          | —               | 3  | 0  | 0  | IIA  | tub2                            | —  | —  |    | 12                 | Liver insufficiency   | —                     | — | — | —  | — |                                                       |
| 22          | —               | 3  | 1  | 0  | IIB  | tub2                            | +  | +  | +  | 15                 | Miliary tuberculosis  | —                     | — | — | —  | — |                                                       |
| 23          | —               | 3  | 1  | 0  | IIB  | tub2                            | +  | +  | +  | 12                 | DOC (local)           | •                     | — | — | —  | • | Lung                                                  |
| 24          | —               | 3  | 1  | 1  | IV   | por                             | —  | —  |    | 24                 | DOC                   | •                     | — | — | —  | • | Lung                                                  |
| 25          | —               | 3  | 0  | 0  | IIA  | pap                             | —  | —  |    | 2                  | DOP                   | —                     | — | — | —  | — |                                                       |
| 26          | —               | 3  | 1  | 0  | IIB  | tub2                            | —  | +  | +  | 2                  | DOP                   | —                     | — | — | —  | — |                                                       |
| 27          | —               | 3  | 1  | 0  | IIB  | tub2                            | —  | —  | +  | 2                  | DOP                   | —                     | — | — | —  | — |                                                       |

**80% de récidive**

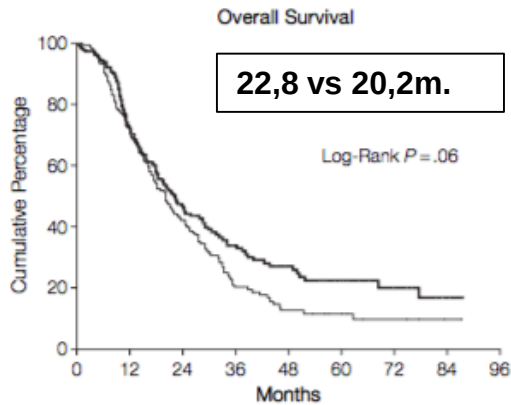
75% de récidive locale

50% de recidive M+ hepatique

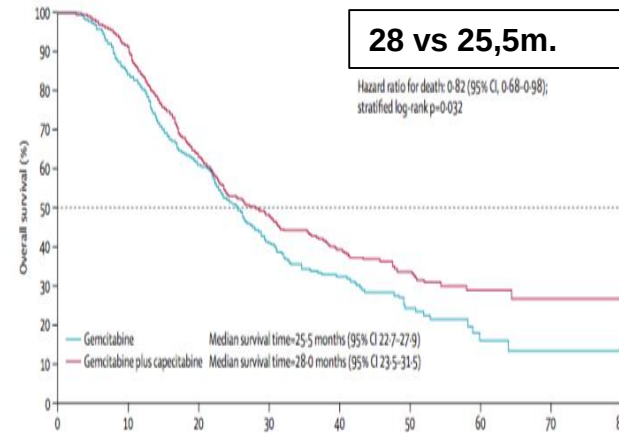
33% de recidive M+ peritoneale

21% de recidive M+ ganglionnaire

# Rationnel du traitement adjuvant



CONKO1



ESPAC4

2001

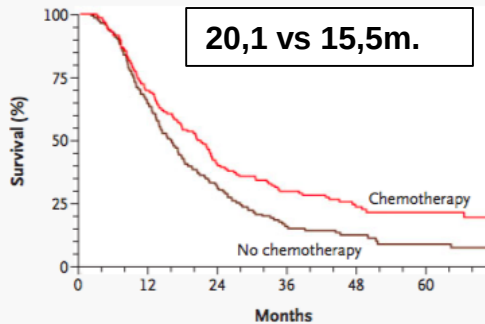
2007

2010

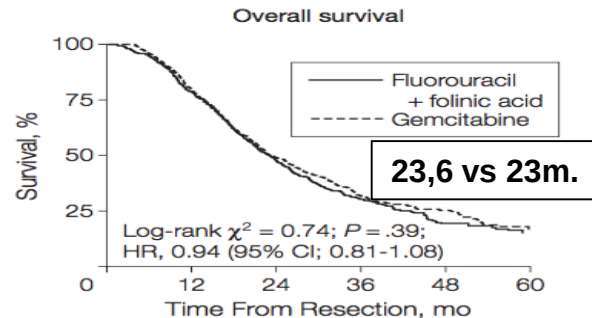
2017

2018

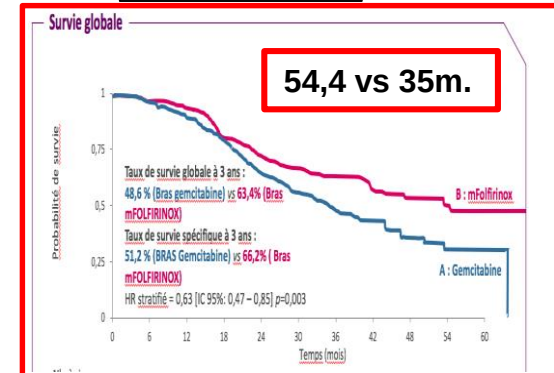
ESPAC1



ESPAC 3



PRODIGE24



# Etude PRODIGE 24

## PRODIGE 24

### FOLFIRINOX vs gemcitabine en adjuvant

- Gemcitabine et/ou fluoropyrimidine (6 mois) : standard en adjuvant

Oettle JAMA 2013, Neoptolemos JAMA 2010, Neoptolemos Lancet 2017

- FOLFIRINOX : standard en 1<sup>ère</sup> ligne métastatique Conroy NEJM 2011

- Résection R0 ou R1
- CA19-9 <180 U/mL dans les 12 semaines après la chirurgie
- Scanner post-opératoire requis.

#### Stratification :

- Centre
- Marge de résection (R0 vs R1)
- CA19-9 ( $\leq 90$  U/mL vs 91-179 U/mL)
- pN0 (<12 vs  $\geq 12$  ganglions examinés) vs pN1

**R** n = 493  
1:1

#### mFOLFIRINOX

- Oxaliplatine 85mg/m<sup>2</sup>
- LV 400mg/m<sup>2</sup>
- Irinotecan 180mg/m<sup>2</sup>,\*
- 5 FU continu 2,4g/m<sup>2</sup> sur 46 heures
- Toutes les 2 semaines, 12 cycles
- \*Réduit à 150 mg/m<sup>2</sup> après le patient 162

#### GEMCITABINE

1000mg/m<sup>2</sup>  
3 semaines /4, 6 cycles

Pour les deux bras :

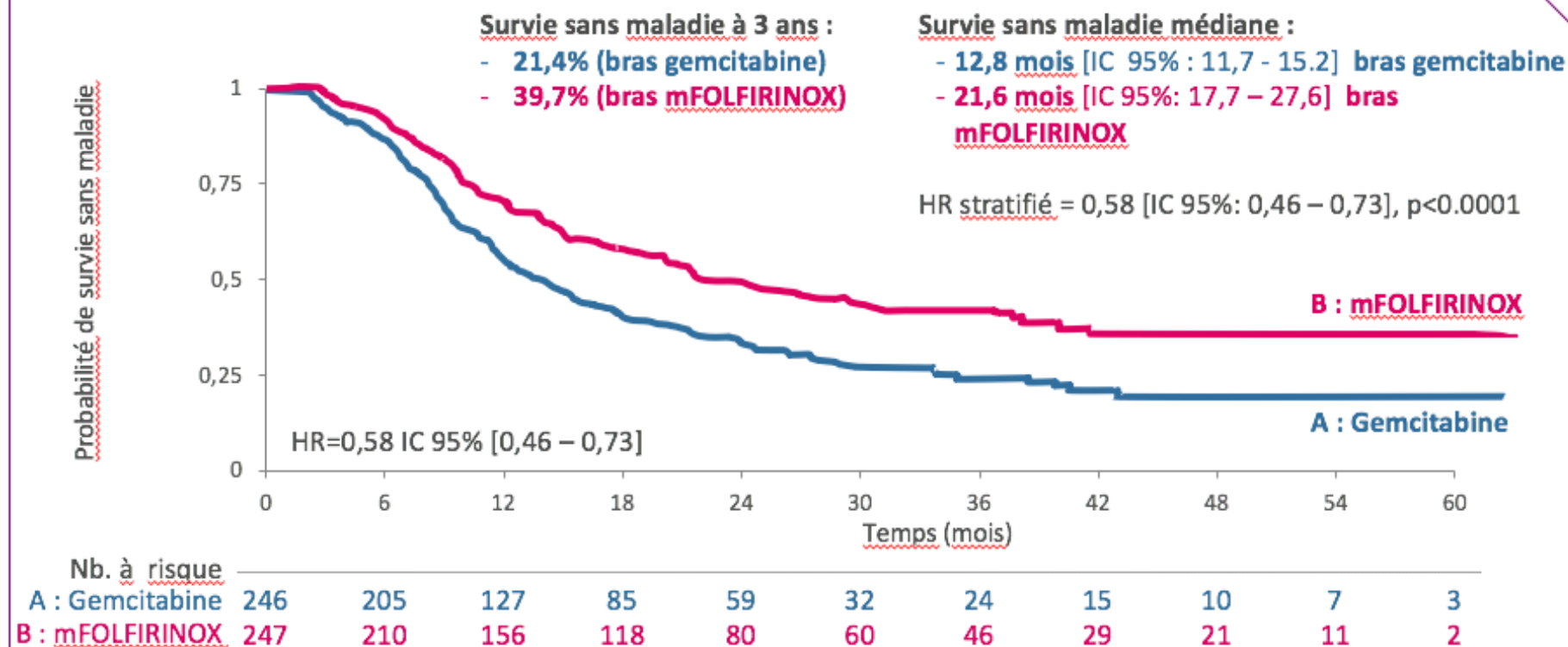
- CT scans : tous les 3 mois
- 6 mois de chimiothérapie

Objectif principal : survie sans maladie à 3 ans

# Etude PRODIGE 24

## PRODIGE 24 FOLFIRINOX vs gemcitabine en adjuvant

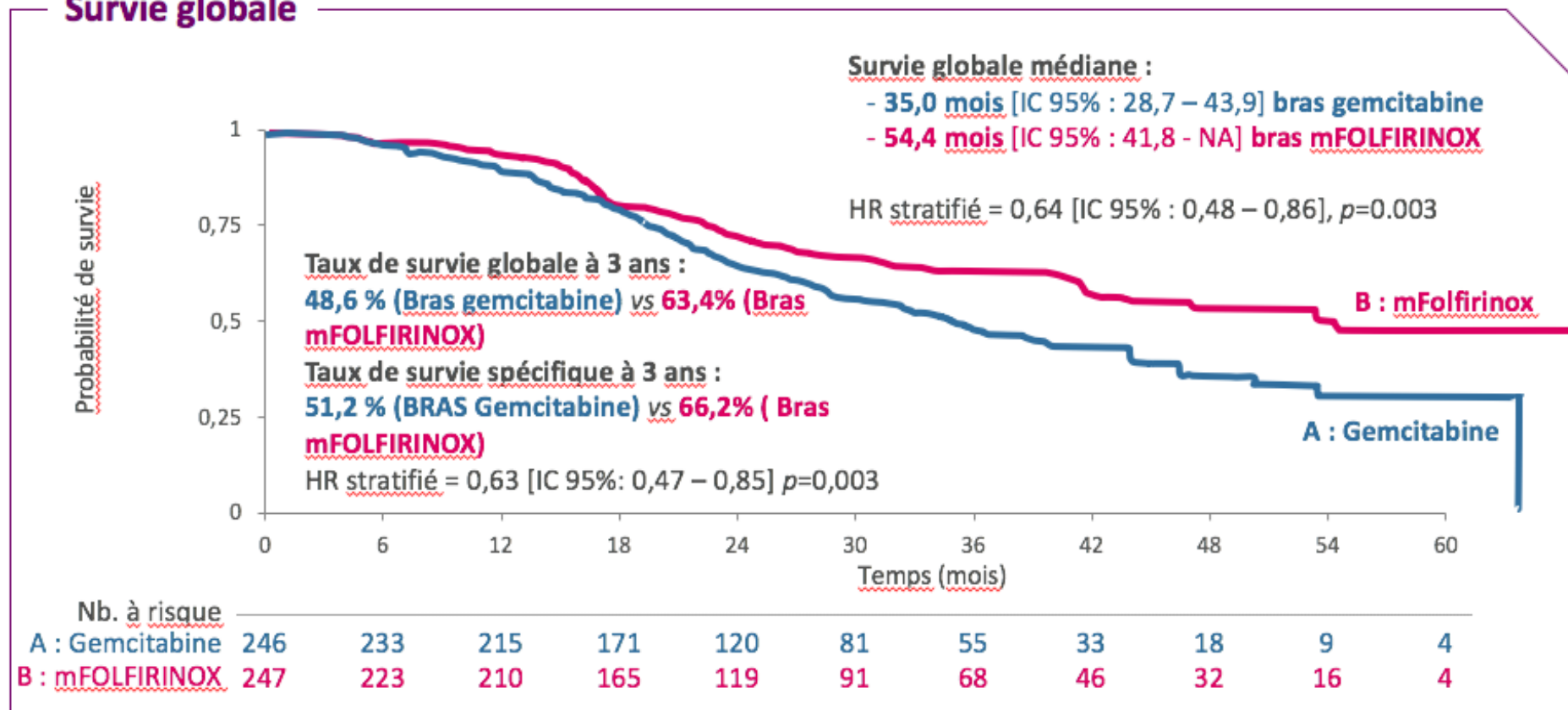
### Survie sans maladie (objectif principal)



# Etude PRODIGE 24

## PRODIGE 24 FOLFIRINOX vs Gemcitabine en adjuvant

### Survie globale



# Etude PRODIGE 24

## PRODIGE 24 FOLFIRINOX vs gemcitabine en adjuvant

### Tolérance

| Effets indésirables (% de patients) | <u>mFOLFIRINOX</u><br>n=238 | <u>Gemcitabine</u><br>n=243 | <i>p</i> |
|-------------------------------------|-----------------------------|-----------------------------|----------|
|                                     | Grades 3/4                  | Grades 3/4                  |          |
| Anémie                              | 3,4 %                       | 2,5 %                       | 0,56     |
| Utilisation de G-CSF                | 59,9 %                      | 3,7 %                       | <0,001   |
| Neutropénie                         | 28,4 %                      | 26,0 %                      | 0,56     |
| Neutropénie fébrile                 | 2,9 %                       | 3,7 %                       | 0,65     |
| Lymphopénie                         | 1,3 %                       | 2,9 %                       | 0,34     |
| Thrombopénie                        | 1,3 %                       | 4,5 %                       | 0,03     |

# Etude PRODIGE 24

## PRODIGE 24 FOLFIRINOX vs gemcitabine en adjuvant

### Tolérance

| Effets indésirables (% de patients)   | mFOLFIRINOX n=238 |            | Gemcitabine n=243 |            | p<br>Tous<br>grades |
|---------------------------------------|-------------------|------------|-------------------|------------|---------------------|
|                                       | Tous grades       | Grades 3/4 | Tous grades       | Grades 3/4 |                     |
| <u>Mucite</u>                         | 33,8 %            | 2,5 %      | 14,9 %            | 0 %        | < 0,001             |
| Diarrhées*                            | 84,4 %            | 18,6 %     | 49 %              | 3,7 %      | < 0,001             |
| Fatigue                               | 84 %              | 11 %       | 77,6 %            | 4,6 %      | 0,003               |
| Vomissements                          | 46 %              | 5 %        | 29 %              | 1,2 %      | < 0,001             |
| Alopécie                              | 27 %              | -          | 19,5 %            | -          | 0,07                |
| Neuropathie périphérique<br>sensitive | 61,2 %            | 9,3 %      | 8,7 %             | -          | < 0,001             |
| Syndrome main-pied                    | 5 %               | 0,4 %      | 0,8 %             | -          | 0,023               |

# Vers un traitement néoadjuvant

## Rationnel

- Laisser un temps d'observation pour évaluer l'agressivité tumorale à l'évolution métastatique précoce (30%)
- Obtenir une réponse tumorale en vue d'une résection R0
- Tester une éventuelle maladie micrométastatique
- Tester la chimiosensibilité de la tumeur et la tolérance au traitement comme élément de sélection pour la chirurgie
- Impossibilité d'administrer le traitement en post opératoire jusque 30% des patients en raison des suites opératoires difficiles

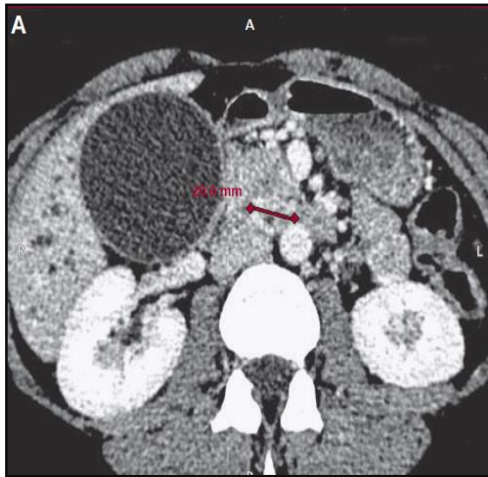
# Etudes prospectives de traitement néoadjuvant

## Essais en cours :

|                   |                                                                                                      |                 |          |          |
|-------------------|------------------------------------------------------------------------------------------------------|-----------------|----------|----------|
| PANACHE-01        | FOLFOX ou FOLFIRINOX puis chirurgie vs. chirurgie seule                                              | 128/32 planifié | En cours | En cours |
| PANDAS-PRODIGE 44 | BRL : chimiothérapie néoadjuvante par mFolfinrox, +/- RCT puis chirurgie                             | 92 planifié     | En cours | En cours |
| NEOPA/NCT01900327 | CRT avec gemcitabine puis chirurgie vs. chirurgie d'emblée                                           | 410 planifié    | En cours | En cours |
| ESPAC-05          | BRL : chimiothérapie néo adjuvante (GemCap ou FOLFIRINOX) ou CRT néoadjuvante vs. chirurgie d'emblée | 100 planifié    | En cours | En cours |
| NCT02451982       | GVAX, cyclophosphamide et nivolumab vs. GVAX et cyclophosphamide                                     | 50 planifié     | En cours | En cours |

# Diagnostic : EEBP incontournable?

## Tumeur solide pancréatique



Bénigne

✓ Masse pseudotumorale de PCC, PAI

Maligne

✓ Tumeur endocrine, hémopathie (lymphome)

✓ Adénocarcinome

✓ Localisé (résécable, borderline, LA)

✓ Métastatique

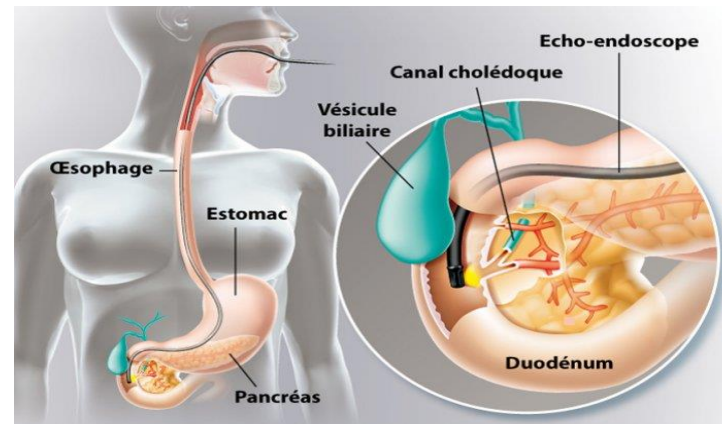
## DIAGNOSTIC

### EEBP avec cytoponction

➤ AG, complications, risque d'échec dans 20 à 30%

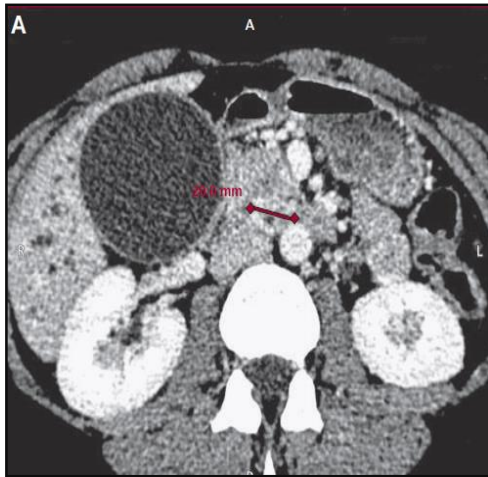
*Voss et al. Gut 2000*

*Tadic et al Dig. Dis. 2008*



# Diagnostic : biopsie liquide comme alternative?

## Tumeur solide pancréatique



Bénigne

✓ Masse pseudotumorale de PCC, PAI

Maligne

✓ Tumeur endocrine, hémopathie (lymphome)

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✓ Localisé (résécable, borderline, LA)

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## DIAGNOSTIC

### EEBP avec cytoponction

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*Voss et al. Gut 2000*

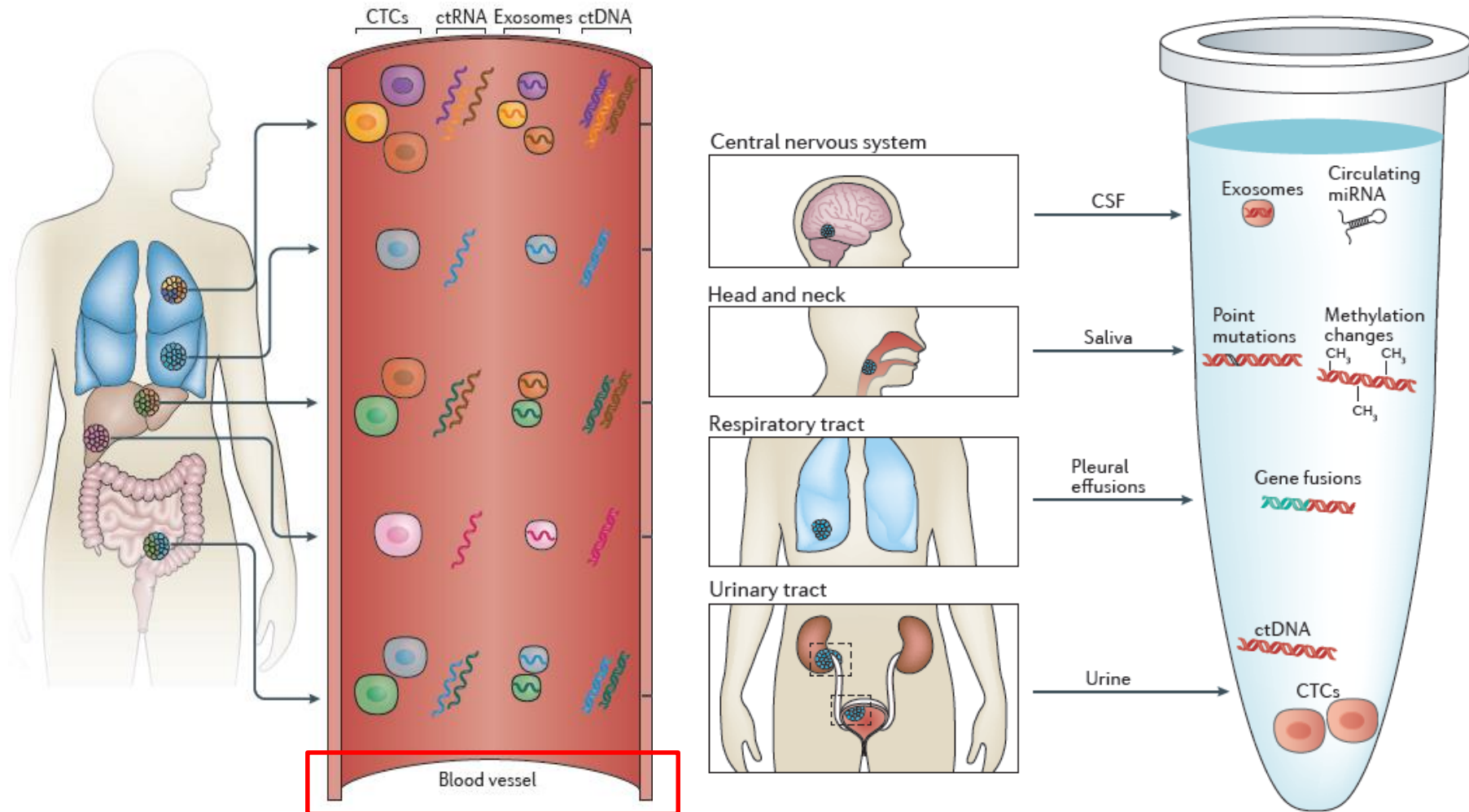
*Tadic et al Dig. Dis. 2008*

### Biopsie liquide (CA19.9, CTC, ADNtumc)

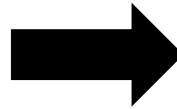
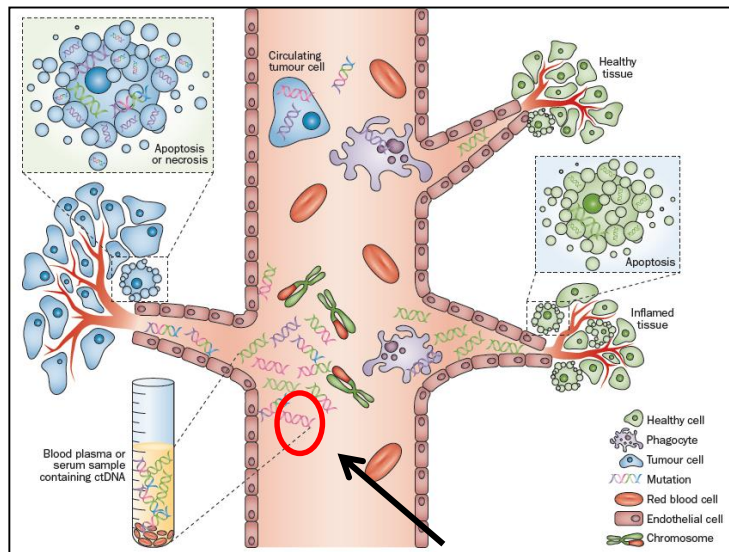
Intérêt des cellules tumorales circulantes (Se de 55% et Sp de 100%)

*Iwanicki Caron et al. American Journal of Gastroenterology 2013*

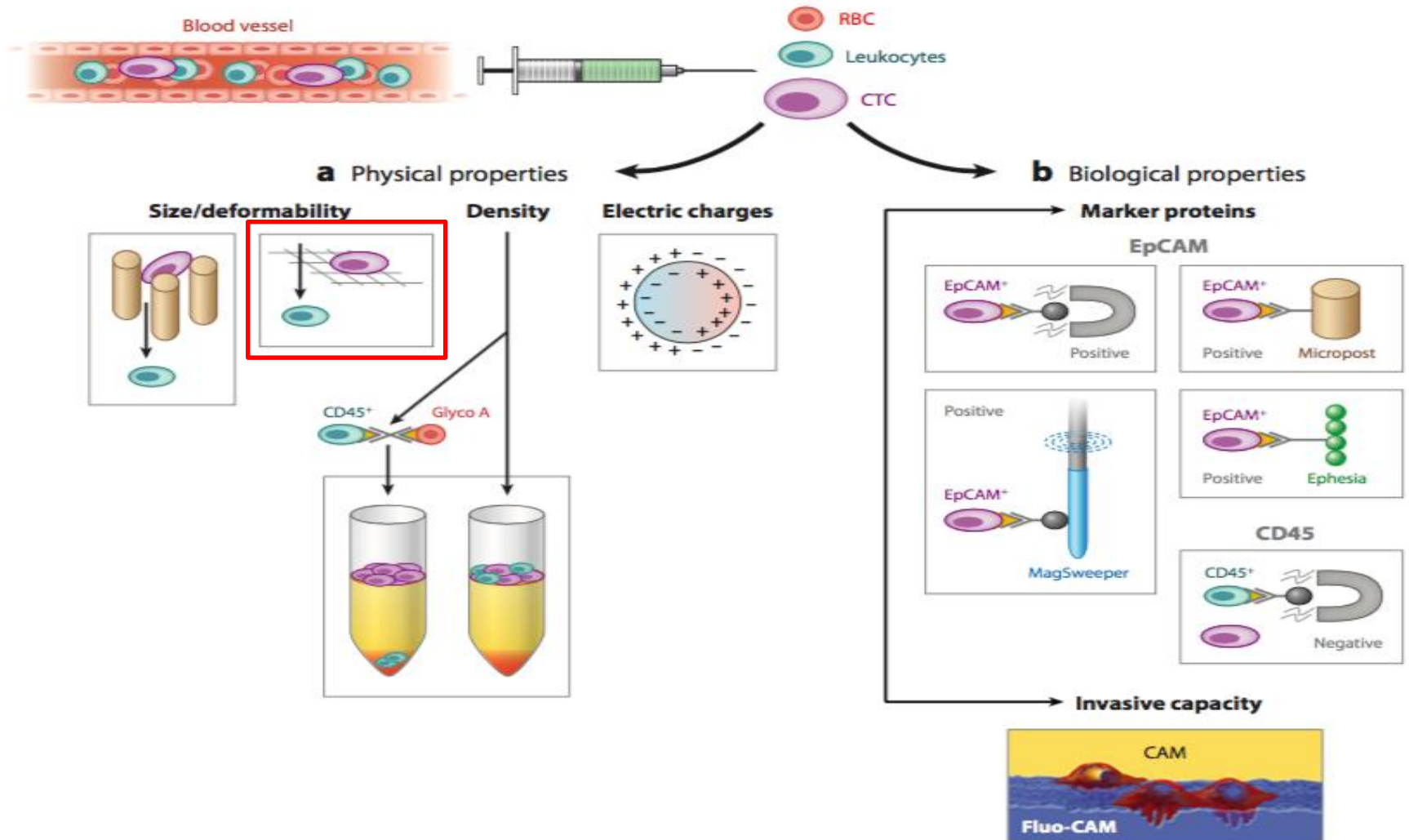
# Biopsie liquide : définitions



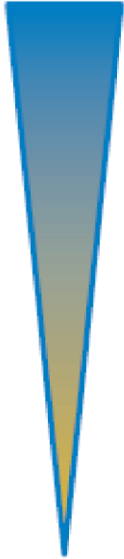
# Biopsie liquide : concept de l'infiniment faible



# Méthodes de détection CTC

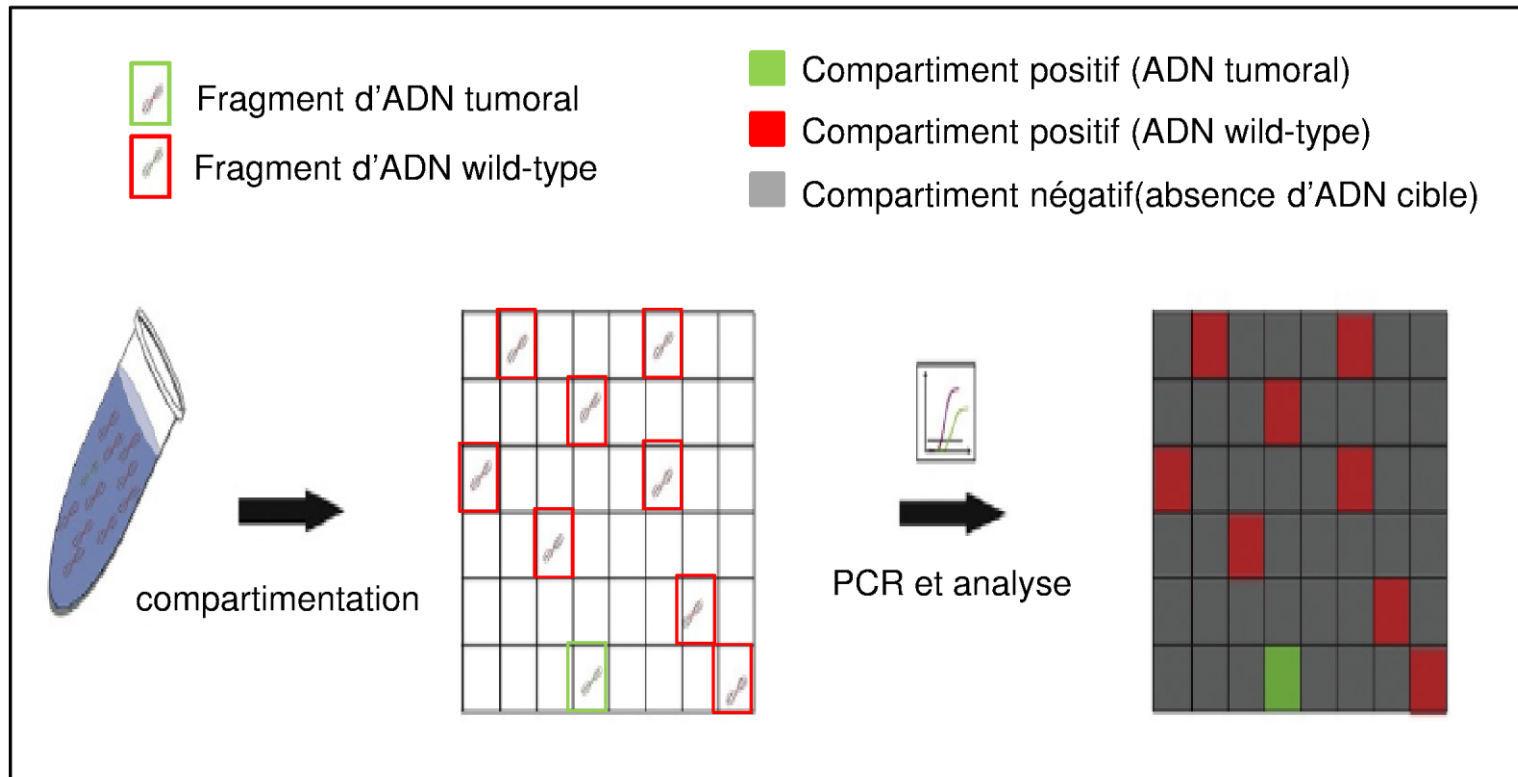


# Méthodes de détection ADNtc

| Technique                                     |                                                                                    | Sensibilité  | Application optimale                   |
|-----------------------------------------------|------------------------------------------------------------------------------------|--------------|----------------------------------------|
| Séquençage Sanger                             |  | > 10 %       | Tissu tumoral                          |
| Pyroséquençage                                |                                                                                    | 5-10 %       | Tissu tumoral                          |
| NGS                                           |                                                                                    | 2 %          | Tissu tumoral                          |
| PCR quantitative                              |                                                                                    | 1 %          | Tissu tumoral                          |
| PCR spécifique d'allèle<br>COLD-PCR           |                                                                                    | 0,1 à 0,01 % | Tissu tumoral, <b>Biopsie liquide</b>  |
| Digitale PCR, NGS optimisé<br>(type CAPP-Seq) |                                                                                    | ≤ 0,01 %     | <b>Biopsie liquide</b> , Tissu tumoral |

*D'après Diaz et al. J Clin Oncol 2014*

# Méthodes de détection : PCR digitale



Modifiée d'après Perkins et al. Adv Clin Chem 2017

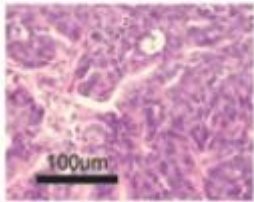
# Design étude EEBP vs biopsie liquide

**Patient(e)s (n=68) :**

Diagnostic récent de tumeur solide pancréatique  
Adressé pour EEBP avec cytoponction

## Biopsie Tissulaire

EEBP avec  
cytoponction  
tumorale



## Biopsie liquide



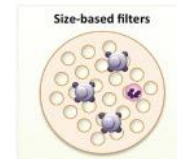
Cellules  
Tumorales  
Circulantes



CA19.9

ADNtumc

ScreenCell®



dPCR  
Qx200® ddPCR  
System (Bio-rad)

Analyse  
Multiplex

# Résultats étude EEBP vs biopsie liquide

**Table 2. Overall accuracy of circulating biomarkers in comparison of EUS-FNA for the diagnosis of pancreatic adenocarcinoma**

|                           | Circulating biomarkers |             |              |                                                       | EUS-FNA<br>% (n)         | EUS-<br>FNA + CA19.9 <sup>a</sup><br>% (n) |
|---------------------------|------------------------|-------------|--------------|-------------------------------------------------------|--------------------------|--------------------------------------------|
|                           | CTC % (n)              | ctDNA % (n) | CA19.9 % (n) | Combination of three<br>biomarkers ( $\geq 2$ ) % (n) |                          |                                            |
| Sensitivity               | 67% (33/49)            | 65% (28/43) | 79% (38/48)  | 78% (31/40)                                           | 73% (38/52) <sup>b</sup> | 100% (48/48)                               |
| Specificity               | 80% (12/15)            | 75% (9/12)  | 93% (14/15)  | 91% (10/11)                                           | 88% (14/16) <sup>c</sup> | 80% (12/15)                                |
| Positive predictive value | 92% (33/36)            | 90% (28/31) | 97% (38/39)  | 97% (31/32)                                           | 93% (38/41)              | 94% (48/51)                                |
| Negative predictive value | 43% (12/28)            | 38% (9/24)  | 58% (14/24)  | 53% (10/19)                                           | 48% (13/27)              | 100% (12/12)                               |
| Accuracy                  | 70% (45/64)            | 67% (37/55) | 83% (52/63)  | 80% (41/51)                                           | 76% (52/68)              | 95% (60/63)                                |

Abbreviations: CTC = circulating tumour cells; ctDNA = circulating tumour DNA; EUS-FNA = Endoscopic ultrasound-guided fine needle aspiration.

<sup>a</sup>The performance of EUS-FNA + CA19.9 combination was based on at least 1 positive result among EUS-FNA and CA19.9.

<sup>b</sup>Suspicious for malignancy were counted as positive for malignancy.

<sup>c</sup>Two false positive cases corresponded to clear-cell renal carcinoma and pancreatic neuroendocrine tumour (PanNET) for which the diagnosis will be adjusted retrospectively.

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# Résultats étude EEBP vs biopsie liquide

**Table 2. Overall accuracy of circulating biomarkers in comparison of EUS-FNA for the diagnosis of pancreatic adenocarcinoma**

|                           | Circulating biomarkers |             |              |                                                    |                          |                                     |
|---------------------------|------------------------|-------------|--------------|----------------------------------------------------|--------------------------|-------------------------------------|
|                           | CTC % (n)              | ctDNA % (n) | CA19.9 % (n) | Combination of three biomarkers ( $\geq 2$ ) % (n) | EUS-FNA % (n)            | EUS-FNA + CA19.9 <sup>a</sup> % (n) |
| Sensitivity               | 67% (33/49)            | 65% (28/43) | 79% (38/48)  | 78% (31/40)                                        | 73% (38/52) <sup>b</sup> | 100% (48/48)                        |
| Specificity               | 80% (12/15)            | 75% (9/12)  | 93% (14/15)  | 91% (10/11)                                        | 88% (14/16) <sup>c</sup> | 80% (12/15)                         |
| Positive predictive value | 92% (33/36)            | 90% (28/31) | 97% (38/39)  | 97% (31/32)                                        | 93% (38/41)              | 94% (48/51)                         |
| Negative predictive value | 43% (12/28)            | 38% (9/24)  | 58% (14/24)  | 53% (10/19)                                        | 48% (13/27)              | 100% (12/12)                        |
| Accuracy                  | 70% (45/64)            | 67% (37/55) | 83% (52/63)  | 80% (41/51)                                        | 76% (52/68)              | 95% (60/63)                         |

Abbreviations: CTC = circulating tumour cells; ctDNA = circulating tumour DNA; EUS-FNA = Endoscopic ultrasound-guided fine needle aspiration.

<sup>a</sup>The performance of EUS-FNA + CA19.9 combination was based on at least 1 positive result among EUS-FNA and CA19.9.

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# Résultats étude EEBP vs biopsie liquide

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|                           | Circulating biomarkers |             |              |                                                       | EUS-FNA<br>% (n)         | EUS-<br>FNA + CA19.9 <sup>a</sup><br>% (n) |
|---------------------------|------------------------|-------------|--------------|-------------------------------------------------------|--------------------------|--------------------------------------------|
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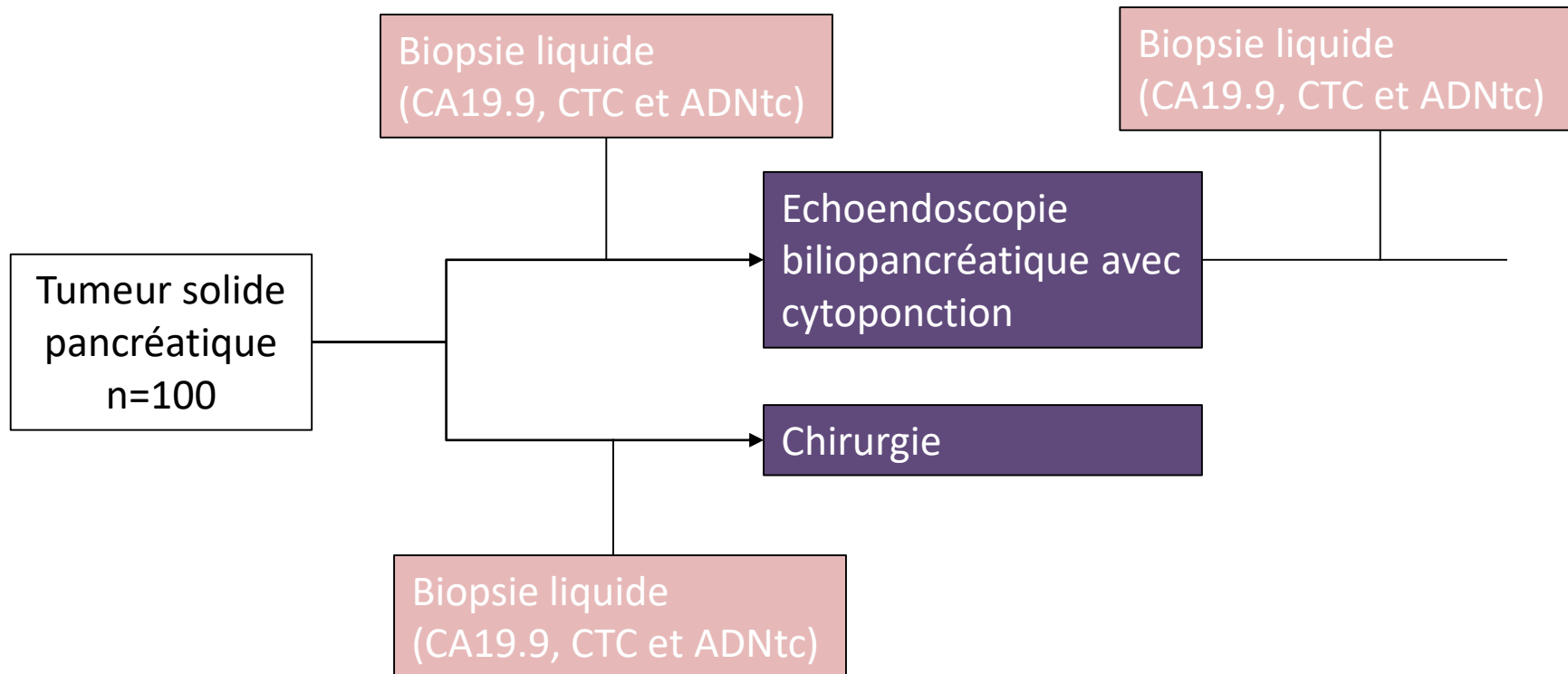
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# Etude prospective CTC pancréas

## Etude prospective CTC pancréas

- Sensibilité et spécificité de la biopsie liquide en comparaison de l'examen anatomopathologique du tissu tumoral



# Take home message

- **Chimiothérapie adjuvante par FOLFIRINOX** : nouveau standard thérapeutique chez les patients en bon EG après résection ADK pancréas (médiane SG 54,4 vs 35 mois)
- **Traitement néoadjuvant** :
  - Rationnel fort
  - Nécessité d'inclusion dans les essais thérapeutiques
    - **Etude PANACHE** : FOLFIRINOX vs FOLFOX vs chirurgie d'emblée en cas de tumeurs résécables d'emblée
    - **Etude PANDAS** : FOLFIRINOX puis chirurgie vs RCT puis chirurgie en cas de tumeurs borderline
- **Biopsie liquide** : alternative séduisante à la biopsie tissulaire
  - plus simple, rapide et moins invasif
  - nécessité d'inclusion dans **l'étude CTC Pancréas**