



Association
Tunisienne de
Réanimation

Comment rédiger le chapitre « Patients et Méthodes »

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JOURNÉE DU PRINTEMPS ATR

Introduction

- ▶ **La Méthodologie: fondement d'un article scientifique**
- ▶ **20% du texte**
- ▶ **Traduit la Pertinence et la rigueur du travail**
- ▶ **Informe:**
 - ▶ Portrait du lieu de l'étude
 - ▶ Période du travail
 - ▶ Echantillon étudié
 - ▶ Méthode d'analyse

Objectifs de la section "méthodologie"

- ▶ **Permet la reproduction de l'étude**
- ▶ **Permet l'interprétation correcte des résultats**
- ▶ **Permet de s'assurer de la qualité des données et de la validité des conclusions**
 - ▶ Pertinence du design de l'étude
 - ▶ Assurance qualité
 - ▶ Prévention et contrôle des biais
 - ▶ Analyse statistique adéquate

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- ▶ **Impliquer un Bio-statisticien /épidémiologiste (écriture / révision)**
 - ▶ **Suivre les directives**
 - ▶ CONSORT (CONsolidate Stabdards Of Reporting Trials)
 - ▶ STROBE (Strengthening the Reorting of Observational studies in Epidemiology)

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- ▶ **« Design » de l'étude:**
 - ▶ **Modalités d'échantillonnage**
 - ▶ **Intervention**
 - ▶ **Critères de jugement**
 - ▶ **Collecte des données (tests de laboratoire, questionnaire)**
 - ▶ **Analyse statistique**

▶ **« Design » de l'étude:**

- ▶ Type d'étude : descriptive, étiologique, évaluation, essai clinique etc./ transversale , rétrospective, prospective, cas clinique etc.

▶ **Modalités d'échantillonnage**

▶ **Intervention**

▶ **Critères de jugement**

▶ **Collecte des données (tests de laboratoire, questionnaire)**

▶ **Analyse statistique**

Types d'étude

3 types d'étude:

- ▶ Étude descriptive:
- ▶ Étude analytique
- ▶ Étude évaluative

Type d'étude

3 types d'étude:

- ▶ Étude descriptive: décrire l'état de santé de la population étudiée
- ▶ Étude analytique: cherche à comprendre un lien entre un facteur de risque et la maladie
- ▶ Étude évaluative: permet d'évaluer une intervention ou un traitement

Type d'étude

**3 types
d'étude:**

Étude
descriptive

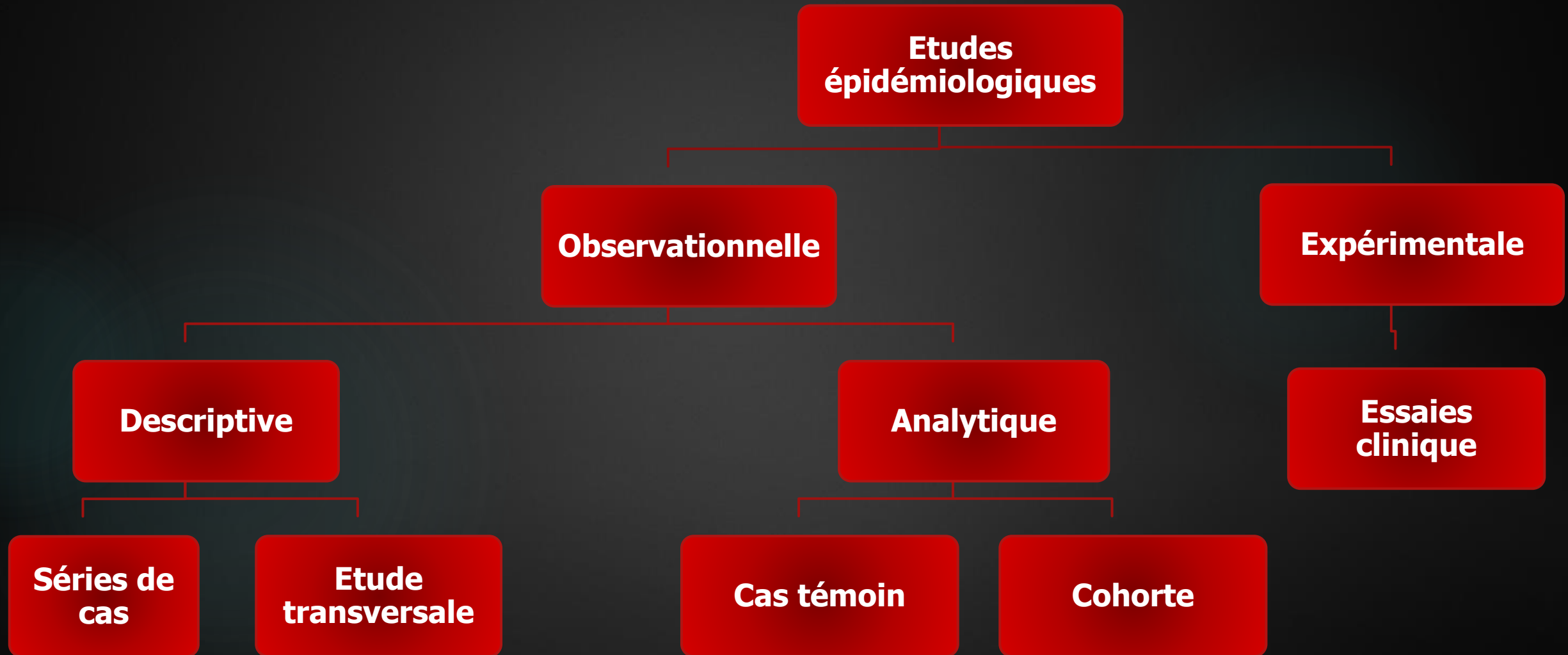
Étude
analytique

Étude
évaluative

Pas de modification
dans la prise en
charge des patients.
Étude
observationnelle

Administration d'un
traitement ou d'une
intervention, Étude
interventionnelle

Types d'étude



Études observationnelles, étude analytiques

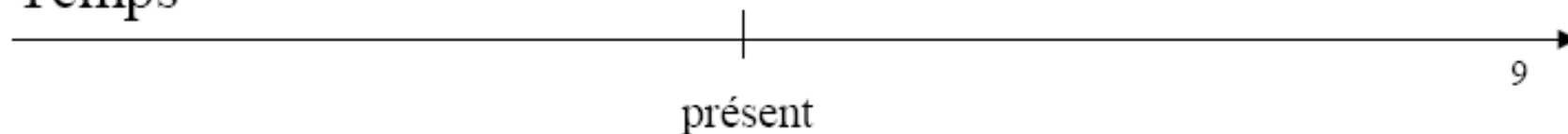
Enquête de cohorte



Enquête cas / témoins



Temps





► **Population étudiée et choix des groupes**

- Personnes/temps/Lieux
- Critères d'inclusion /non inclusion/ d'exclusion:
- Méthodes de sélection / recrutement : variables selon le type d'étude (tirage au sort, recrutement consécutif, appariement des témoins aux cas etc.)
- Consentement des patients!

Randomisation

- ▶ **Le type de randomisation:**

- ▶ Randomisation simple
- ▶ Randomisation par bloc
- ▶ Randomisation stratifié

- ▶ **La méthode de randomisation utilisée:**

- ▶ Tirage au sort
- ▶ Enveloppe numérotée
- ▶ Appel téléphonique centralisé
- ▶ Logiciel de randomisation ...

Interventions: « étude interventionnelle »

▶ **Détails sur les différentes intervention selon les groupes**

- ▶ Molécules (traitement, placebo, doses)
- ▶ Techniques, formation, matériel de formation et d'information, standardisation

Critères de jugement

- ▶ **Critère de jugement majeur clairement définie+++**

- ▶ Un seul critère majeur ! (ECR): mortalité à j28,,,

- ▶ **Les critères secondaires**

- ▶ Ne pas dépasser 2-3 critères secondaires
 - ▶ Durée de séjours ; durée de VM ATB,,,

Data management

- ▶ **Définir les variables recueillies**

- ▶ PAVM, SDRA, état de choc septique, hyperleucocytose,,,

- ▶ **Techniques de mesure utilisées**

- ▶ Dosages médicamenteux

- ▶ Techniques de calibrations

Table 1. Definitions.

Case definitions

Community-acquired pneumonia (CAP) (working diagnosis): The presence of at least two of the diagnostic clinical criteria and in-hospital treatment with antibiotics for clinically suspected CAP as documented by the treating physician. Patients with two or more criteria and an obvious nonrespiratory source of infection were not considered to have a working diagnosis of CAP, nor were patients who had recently been hospitalized (for >48 hours in the previous 2 weeks) or who resided in long-term care facilities.

Radiologically confirmed CAP: A working diagnosis of CAP plus the presence of a new or increased infiltrate on chest radiography or computed tomography (CT) and at least two other clinical criteria.

Diagnostic clinical criteria

Cough

Production of purulent sputum or a change in the character of sputum

Temperature >38°C or <36.1°C

Auscultatory findings consistent with pneumonia, including rales, evidence of pulmonary consolidation (dullness on percussion, bronchial breath sounds, or egophony), or both

Leukocytosis (>10×10⁹ white cells per liter or >15% bands)

C-reactive protein level more than 3 times the upper limit of the normal range

Dyspnea, tachypnea, or hypoxemia

New or increased infiltrate on chest radiography or CT scan

Intervention strategies*

Beta-lactam strategy: Preferred empirical treatment with amoxicillin, amoxicillin plus clavulanate, or a third-generation cephalosporin. Penicillin was not allowed as empirical beta-lactam monotherapy.

Beta-lactam–macrolide strategy: Preferred empirical treatment with penicillin, amoxicillin, amoxicillin plus clavulanate, or a third-generation cephalosporin in combination with azithromycin, erythromycin, or clarithromycin

Fluoroquinolone strategy: Preferred empirical treatment with moxifloxacin or levofloxacin

* Strategies were based on the recommendations in the Dutch guideline on treatment of CAP that was available before the start of the study.²³

Analyses statistiques

► Taille de l'échantillon

- Les méthodes utilisées pour faire le calcul du NSN « nombre de sujet nécessaire »
- Puissance de l'étude $P = 1 - \beta$ (80% minimum)
 - β = probabilité d'avoir un faux négatif (15-20%)
 - α = probabilité que la différence soit due au hasard (5%)
 - prévalence estimative de la pathologie
- Des données de la littérature pour supporter les hypothèses

Analyses statistiques

- ▶ **Les tests statistiques utilisés**
 - ▶ Comparaison de moyenne
 - ▶ Comparaison des mortalités,,,,
- ▶ **Niveau de signification pour les tests statistiques spécifiques**
- ▶ **Effet des analyses intermédiaires sur l'étude!**
- ▶ **Stratégie de traitement des données manquantes, les écarts par rapport au protocole**

Analyses statistiques

- ▶ **Les méthodes d'analyse des données**
- ▶ **Les personnes incluses dans l'analyse:**
 - ▶ Analyse en intension de traiter: Analyse de tous les patients randomisés dans le groupe où ils furent randomisés
 - ▶ Analyse per protocole: Analyse uniquement des patients qui ont été traités en pleine conformité avec le protocole. Les inclusions à tort, les patients non observants, les patients traités avec le traitement de l'autre groupe sont exclus de l'analyse
 - ▶ **Analyse en traitement reçu:** Les patients sont analysés en fonction de la nature du traitement qu'ils ont reçu, même s'il ne s'agit pas du traitement qui leur fut alloué par la randomisation

Analyses statistiques

- ▶ **Procédures pour irrégularités: données manquantes, sujet non-conformité, ou écarts au protocole**
- ▶ **statistiques descriptives (par exemple, les moyennes, les tables de fréquences,)**
- ▶ **Test d'hypothèse:**
 - ▶ hypothèses statistiques (implicite)
 - ▶ tests statistiques (par exemple, t-test, test de Wilcoxon, modèle de régression)
 - ▶ niveau de signification
 - ▶ Uni vs Bilatérale
 - ▶ Présentation des valeurs p et les IC

Analyses statistiques

- ▶ Hiérarchie des analyses (univariée, multivariée, ...)
- ▶ Analyse descriptive
- ▶ Méthodes d'analyse intermédiaire
- ▶ Analyse des sous groupes
- ▶ Le logiciel de statistique utilisé
- ▶ Enregistrement des essais cliniques www.ClinicalTrials.gov

Quelques conseils

- ▶ **Impliquer un statisticien**
- ▶ **Suivre les directives, CONSORT, STROBE**
- ▶ **Utiliser les articles publiés à titre d'exemple pour le style et le format**
- ▶ **Utiliser des références efficaces et appropriées**
- ▶ **La Clarté est primordiale**
- ▶ **Eviter de mettre des résultats dans ce chapitre**

Retenir

- ▶ **Reproductibilité**
- ▶ **Clarté**
- ▶ **Qualité**
- ▶ **Interprétation**

Bibliographies

- ▶ CONSORT

- ▶ <http://www.consort-statement.org/>

- ▶ **STROBE**

- ▶ **http://www.strobe-statement.org/index.php?id=strobe-singel-news-view&tx_ttnews%5Btt_news%5D=1357&cHash=52334cb1c3299d67f6703e13a566035d**



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item	Checklist item	Reported on page No
	No		
	1a	Identification as a randomised trial in the title	_____
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	_____
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	_____
	2b	Specific objectives or hypotheses	_____
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	_____
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	_____
Participants	4a	Eligibility criteria for participants	_____
	4b	Settings and locations where the data were collected	_____
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	_____
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	_____
	6b	Any changes to trial outcomes after the trial commenced, with reasons	_____
Sample size	7a	How sample size was determined	_____
	7b	When applicable, explanation of any interim analyses and stopping guidelines	_____
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	_____
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	_____
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	_____
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	_____
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	_____

Table 1

The STROBE Statement—checklist of items that should be addressed in reports of observational studies.

	Item number	Recommendation
Title and Abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants (b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed Case-control study—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8 ^a	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) Cohort study—If applicable, explain how loss to follow-up was addressed Case-control study—If applicable, explain how matching of cases and controls was addressed Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses