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THÈSE

Pour obtenir le diplôme de doctorat

Spécialité RECHERCHE CLINIQUE, INNOVATION TECHNOLOGIQUE, SANTE PUBLIQUE

Préparée au sein de l'Université de Caen Normandie

Etude de l'effet centre en dialyse péritonéale

Présentée et soutenue par
Sonia FOURRE

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Abréviations

CCI : Coefficient de Corrélation Intraclasse

CH : Centre Hospitalier

CHU : Centre Hospitalier Universitaire

Cs-HR : Caus specific Hasard Ratio

DFG : Débit de Filtration Glomérulaire

DP : Dialyse Péritonéale

DPA : Dialyse Péritonéale Assistée

DPCA : Dialyse Péritonéale Continue Ambulatoire

EDTA : European Renal Association – European Dialysis and Transplant Association

HAS : Haute Autorité de Santé

HD : Hémodialyse

HR : Hazard Ratio

IC : Intervalle de Confiance

ICC : Index de Comorbidité de Charlson

IDE : Infirmier(e) Diplômé(e) d'Etat

IIQ : Intervalle Interquartile

IMC : Indice de Masse Corporelle

INSEE : Institut national de la statistique et des études économiques (INSEE).

IRA : Insuffisance Rénale Aiguë

IRC : Insuffisance rénale chronique

IRCT : Insuffisance rénale chronique Terminale

ISPD : International Society for Peritoneal Dialysis

KDIGO : Kidney Disease: Improving Global Outcomes

MRC : Maladie Rénale Chronique

OR : Odds Ratio

Pmh : par million d'habitants

RDPLF : Registre de Dialyse Péritonéale de Langue Française

REIN : Réseau Epidémiologie et Information en Néphrologie

RR : Risque Relatif

SFNDT : Société Française de Néphrologie Dialyse Transplantation

SSR : Soins de Suite et Réadaptation

VAD : Visite à domicile

VPV : Variation proportionnelle de la variance

1. Introduction

1.1. La maladie rénale chronique

La maladie rénale chronique (MRC), est définie par la diminution irréversible du débit de filtration glomérulaire (DFG). Selon un consensus international, *Kidney Disease: Improving Global Outcomes* (KDIGO), la MRC est définie par l'existence depuis plus de 3 mois [1] :

- d'un débit de filtration glomérulaire (DFG) inférieur à 60 ml/ min/1,73 m2
- et/ou d'une anomalie rénale morphologique ou histologique « cliniquement significative »
- et/ou d'une anomalie biologique sanguine ou urinaire secondaire à une atteinte rénale (protéinurie, albuminurie, leucocyturie, hématurie)

On estime à 850 millions dans le monde et à 3 millions en France, le nombre de personnes souffrant d'une MRC. Les principales causes de la MRC sont la néphropathie diabétique et la néphroangiosclérose.

Différents stades de sévérité sont définis permettant de proposer une prise en charge stratifiée (Tableau 1).

Tableau 1. Classification des stades d'évolution de la maladie rénale chronique (HAS 2012) [2]

Stade	DFG (ml/min/1.73m^2)	Définition
I	>90	Maladie rénale chronique avec DFG normal ou
II	Entre 60 et 89	Maladie rénale chronique avec DFG légèrement diminué
III	Stade 3a : entre 45 et 59 Stade 3b : entre 30 et 44	Insuffisance rénale chronique modérée
IV	Entre 15 et 30	Insuffisance rénale chronique sévère
V	<15	Insuffisance rénale chronique terminale

1.2. L'insuffisance rénale terminale

L'insuffisance rénale terminale (IRT) est définie par un DFG <15ml/min/1.73m2 ou par l'existence d'un traitement de suppléance rénale [2]. L'épuration extra-rénale et la transplantation rénale sont à ce jour les seuls traitements de suppléance disponibles.

En France, les données du registre Réseau Epidémiologie et Information en Néphrologie (REIN) permettent d'évaluer la prévalence et l'incidence de l'IRT sous traitement de suppléance. Le nombre de patients atteignant le stade V mais qui ne sont pas traités par dialyse ou greffe rénale n'est pas connu. En 2017, 11 543 personnes ont commencé un traitement de suppléance, soit une incidence de 172 par million d'habitants (pmh). 11 006 sujets ont débuté un traitement par dialyse (164 pmh) et 537 par greffe rénale préemptive (8 pmh). L'âge médian au démarrage du traitement de suppléance était de 70,5 ans. Au 31 décembre 2017, la prévalence était de 1294 pmh [4].

1.3. Les traitements

1.3.1. L'épuration extra-rénale

Il est habituel de séparer les traitements par épuration extra-rénale en traitement du domicile et traitement en centre. Il existe deux méthodes d'épuration extrarénale : l'hémodialyse (HD) et la dialyse péritonéale (DP). L'hémodialyse est le plus souvent réalisée en centre à raison de séances de 4 heures 3 fois par semaine. La grande majorité des centres de traitement proposent des séances diurnes, les séances nocturnes en centre étant peu développées. La mise sur le marché de générateurs peu encombrants, simples d'utilisation, a permis le développement récent de l'hémodialyse à domicile. En DP on utilise la cavité naturelle péritonéale. Un cathéter inséré dans la cavité péritonéale permet l'injection du dialysat. La DP est une technique quasi exclusivement du domicile.

1.3.2. La transplantation rénale

La transplantation rénale, est associée à une meilleure qualité de vie pour les patients comparativement au traitement par dialyse. Elle doit être proposée à tous les patients sans contre-indication et qui souhaitent recevoir ce traitement. En France, la greffe peut être réalisée à partir du prélèvement d'un rein d'un donneur anonyme décédé ou bien d'un don provenant d'un proche. La transplantation nécessite la prise d'un traitement immunosuppresseur destiné à éviter le rejet du greffon. La transplantation peut être réalisée chez un patient en IRC au stade V et/ou après le début du traitement par dialyse. En 2017, 3782 patients ont bénéficié d'une transplantation rénale [3].

1.3.3. Le traitement conservateur

Le traitement conservateur est une alternative au traitement de suppléance [7]. Le traitement conservateur est une forme de traitement palliatif de l'insuffisance rénale chronique ne comprenant pas de dialyse. L'objectif est de ralentir le plus possible l'évolution naturelle de la MRC, de réduire les complications et de traiter les symptômes qui rendent le patient inconfortable. Il a pour but de maintenir le patient dans un état général compatible avec son projet de vie sans traitement de suppléance [8-9]. La décision du traitement conservateur doit faire l'objet d'une décision partagée entre l'équipe de soin et le patient [10].

1.4. Parcours de soins : prise en charge intégrée

Au cours de son existence un patient atteint d'une MRC au stade de l'insuffisance rénale terminale pourra être traité par toutes les modalités thérapeutiques disponibles.

A partir du stade IV, le patient doit pouvoir bénéficier d'une information et présentation des différentes thérapeutiques possibles, appelées « présentation de méthodes » ou « information pré-suppléance ». L'information doit être proposée précocement dans le parcours du patient pour permettre la préparation au traitement choisi ou adapté aux contre-indications médicales, et éviter ainsi les prises en charge en urgence qui sont associées à une augmentation du risque de mortalité comparativement à la prise en charge planifiée [9].

Le parcours du patient dépend de la rapidité de l'évolution de la MRC, des évènements prévisibles ou non et de ses choix. Les phases de transition entre les modalités thérapeutiques peuvent être choisies ou subies. Le traitement doit être ainsi pensé dans sa globalité afin de proposer au patient une prise en charge adaptée à ses choix et à son état de santé. La MRC a été reconnue par la Haute Autorité de Santé (HAS) comme l'une des quatre pathologies prioritaires pour la mise en place d'un parcours de soins [2].

2. La dialyse péritonéale

2.1. Généralités

En DP, un cathéter est inséré dans la cavité péritonéale et permet d'utiliser le péritoine pour épurer le sang du patient. Le dialysat est injecté dans la cavité péritonéale par le cathéter. Le temps de stase du dialysat permet des échanges d'eau et de soluté par des phénomènes de diffusion et de convection.

La dialyse péritonéale est une méthode d'épuration extrarénale du domicile qui se pratique habituellement quotidiennement. Le patient et/ou sa famille sont formés par une équipe experte en DP [10]. Il bénéficie d'un suivi régulier par l'équipe médicale et infirmière dans le centre de traitement environ toutes les 6 à 8 semaines [11]. En France, réglementairement, les prescriptions sont réévaluées tous les deux mois par le néphrologue en charge du patient [11].

2.2. Epidémiologie

La dialyse péritonéale est peu utilisée en France, elle représente 8.5 % de l'ensemble des traitements de suppléance. Il existe une hétérogénéité de l'utilisation de la DP sur le territoire national, la part de la DP variant entre les régions [4]. Il existe aussi des disparités entre les centres de traitement en ce qui concerne leurs caractéristiques et leurs pratiques.

Une récente enquête réalisée auprès des néphrologues français répertorie certains freins au développement de la DP [12] comme les difficultés de prise en charge des patients âgés en Soins de Suite et Réadaptation (SSR), la crainte d'une épuration insuffisante ou bien les difficultés liées à la pose du cathéter de DP (chirurgien dédié, délai, difficultés relatives à l'anesthésie).

Cependant, une autre équipe française rapporte que le faible taux de DP en France ne peut s'expliquer par un avis négatif sur cette modalité de dialyse par les néphrologues français [13].

La dialyse à domicile est sous utilisée en France en comparaison à d'autres pays développés. La dialyse péritonéale est pourtant une modalité de dialyse économique et correspond aux attentes de nombreux patients [14-15]. Elle évite également les déplacements plusieurs fois par semaine et elle peut être plus compatible avec une activité professionnelle et les voyages par rapport à l'HD en centre.

L'hétérogénéité d'utilisation de la DP existe aussi au niveau international et pourrait en partie être liée aux différences des systèmes de santé [16].

2.3. Les différentes modalités

Cette technique pratiquée à domicile peut être réalisée de jour grâce à des échanges manuels, c'est la Dialyse Péritonéale Continue Ambulatoire (DPCA) ou bien de nuit grâce à un cycleur et on parle de Dialyse Péritonéale Automatisée (DPA). Le choix de l'une ou l'autre modalité est fait en fonction du désir et des contraintes exprimées par le patient.

La Dialyse Péritonéale Continue Ambulatoire

Dans cette modalité, 3 à 4 échanges sont réalisés manuellement le jour. La connexion au cathéter d'une double poche en Y permet, en une seule manipulation, dans un premier temps le drainage de la cavité péritonéale et dans un second temps l'injection du dialysat. Cette modalité suppose donc plusieurs manipulations sur le cathéter. L'activité professionnelle peut être moins compatible avec des échanges diurnes.

La Dialyse Péritonéale Automatisée

En DPA, les échanges sont réalisés la nuit, grâce à un cycleur. Un programme permet les drainages et injections automatisées pendant le sommeil du patient qui se branche le soir et se débranche le matin. La DPA permet aux patients d'être affranchis des contraintes des échanges diurnes.

Une revue de littérature a recensé les études ayant comparé les deux modalités, DPA et DPCA [17]. Il est difficile de conclure que la modalité de DP a un effet significatif sur la survie technique ou la survie du patient. Le risque d'infection péritonéale n'est pas influencé par la modalité de dialyse péritonéale. Une étude brésilienne prospective ne montrait pas de différence entre l'échec technique et le délai avant la première péritonite quelle que soit la modalité [18]. En revanche, dans ce travail, la DPA était associée à une meilleure survie du patient par rapport à la DPCA. La modalité de DP n'était pas associée au risque de péritonite dans une étude australienne [19].

2.4. La formation à la dialyse péritonéale

La formation et l'éducation des patients à la dialyse péritonéale doit être réalisée sous le contrôle d'un néphrologue, par des infirmières expertes [10]. Le patient, l'aidant familial ou un infirmier à domicile reçoivent une formation concernant les soins d'émergence (orifice de sortie du cathéter) indispensables pour éviter l'infection péritonéale ainsi que les connexions et déconnexions du cathéter dans des conditions aseptiques. L'objectif est d'éviter la contamination de la cavité péritonéale et les infections. Les conduites à tenir en cas d'anomalie de coloration du liquide, d'alarmes, et de problèmes de santé en dialyse sont également abordées. La formation des patients [20], des aidants et des professionnels [21] a fait l'objet de recommandations par l'ISPD.

Une étude internationale, réalisée il y a un peu plus d'une dizaine d'année, avait mis en évidence, non seulement la grande variation du déroulement des programmes de formation de DP entre les pays eux-mêmes, mais également entre les centres à l'intérieur d'un même pays. [22].

En Australie, une récente étude réalisée en 2018 rapporte que 86% des centres utilisent un programme standardisé et le temps passé varie de 15h à 100 h. Dans cette étude, seulement la moitié des centres utilisaient un programme écrit pour la formation des infirmières [21].

Récemment, il a été suggéré que l'évaluation et la formation des patients à domicile pourraient améliorer leurs connaissances [23].

2.5. Les principaux évènements en dialyse péritonéale

Outre le décès et l'arrêt de la méthode de traitement par greffe rénale, les deux principaux évènements en dialyse péritonéale sont l'échec du traitement habituellement défini par le transfert en hémodialyse et l'infection péritonéale.

2.5.1. L'échec du traitement

L'échec technique est une cause fréquente d'arrêt de la DP défini par convention par un transfert en hémodialyse d'une durée supérieure à 180 jours [24]. Le risque d'échec technique est plus élevé dans l'année suivant l'initiation du traitement par DP [25-27]. Lorsque le transfert a une durée supérieure à 180 jours la probabilité d'être à nouveau traité par la dialyse péritonéale dans l'année suivant le changement de modalité thérapeutique est de 3%.

La définition de l'échec de la dialyse péritonéale ne fait pas l'objet d'un consensus. En outre l'échec précoce est, pour certains, défini par un transfert en HD dans les 6 premiers mois du traitement et pour d'autres dans la première année de la dialyse péritonéale [28].

Nous avons montré que, en France, 6,3% des sujets débutant la dialyse péritonéale sont transférés en HD dans les 6 premiers mois du traitement [29]. Il aussi admis que les causes d'un arrêt précoce de la DP sont différentes de celles à l'origine d'un échec tardif de la DP [30].

Le transfert en hémodialyse est un évènement ponctuel dans le parcours du patient, la phase de transition incluant le moment du transfert doit être anticipée pour optimiser le parcours du patient.

Notre équipe a montré que le transfert d'une méthode à l'autre était trop souvent fait dans un contexte d'urgence, de façon non planifiée et au cours d'une hospitalisation, ne permettant pas le maintien au domicile [31]. Une étude française de 2009 a cependant montré que l'échec technique n'était pas un frein au développement de la dialyse péritonéale en France [32].

De nombreux facteurs contribuent à l'échec de la dialyse péritonéale [29,33]. Parmi les plus fréquents, on retrouve l'infection péritonéale, la dysfonction du cathéter, les problèmes psychologiques liés à l'acceptation du traitement, l'ultrafiltration inefficace, la dialyse inadéquate et la malnutrition.

2.5.2. L'infection péritonéale

Selon l'International Society for Peritoneal Dialysis [34], l'infection péritonéale est définie par un dialysat trouble et/ou des douleurs abdominales et la présence de globules blancs supérieurs à 100/mm3 (après un temps de contact de 2 heures), avec au moins 50 % de polynucléaires neutrophiles.

Les soins d'émergence du cathéter ont pour objectif de diminuer la contamination bactérienne du péritoine, en diminuant le portage cutané. Une étude espagnole a montré que, lors d'une infection péritonéale à staphylococcus aureus (SA), l'émergence du cathéter était colonisée par une SA ayant le même phénotype et génotype [35].

L'infection d'émergence est définie par l'ISDP [36] par un écoulement purulent autour de l'émergence.

Des recommandations ont été rédigés dans l'objectif de réduire l'incidence des péritonites en dialyse péritonéale [37].

Nous savons que des facteurs individuels tels que l'âge du patient, le diabète et l'indice de masse corporelle sont associés à un risque plus élevé d'avoir une péritonite [38-40].

La dialyse péritonéale est une méthode du domicile, l'éducation du patient et/ou des aidants sont des composantes de la réussite de la méthode et de la prévention des complications.

Il existe des recommandations établies par l'ISPD à destination des équipes concernant l'éducation du patient, l'hygiène des mains, l'utilisation d'un savon antibactérien et d'un antiseptique pour le nettoyage de l'émergence [41]. La répétition des séances d'éducation dans le temps est indispensable pour la compliance des patients. La non adhérence des patients est associée au risque de développer une péritonite [42]. Le temps dédié à l'éducation est associé au risque de péritonites. Il a été montré que les patients ayant reçu un entraînement d'une durée supérieure à 15 heures présentaient une incidence de péritonite significativement inférieure à celle des patients en ayant eu une formation plus courte [43].

Des études ont montré que l'infection péritonéale peut provoquer des altérations de la membrane péritonéale, et être à l'origine d'un transfert en hémodialyse ou du décès du patient [44-46]. L'infection péritonéale peut aussi affecter la fonction rénale résiduelle [47]. Il a également été démontré que le risque d'infection péritonéale était une préoccupation et un sujet d'inquiétude pour les patients [48]. La crainte de la péritonite influence le choix du patient lors de la décision de la modalité d'épuration extrarénale [49].

2.6. La dialyse péritonéale assistée

Les sujets devant débuter la dialyse sont, dans la majorité des cas, âgés et présentent des comorbidités pouvant constituer un frein à l'utilisation de la dialyse péritonéale [50-53].

Le manque d'autonomie, l'incapacité fonctionnelle telle que le manque de force, les troubles de la vision ou de l'audition ainsi que les dysfonctions cognitives peuvent être compensées par la mise en place d'une assistance qui permet d'accroître l'éligibilité des patients pour la DP [54,55]. Ce traitement, comparé à l'hémodialyse en centre, peut offrir des avantages en termes de qualité de vie en réduisant

les transports, en évitant l'instabilité hémodynamique liée aux séances d'hémodialyse et la fatigue liée à la sensation de « lessivage post traitement » (wash-out des anglosaxons) [51,52].

Dans différents pays à travers le monde, dont la France, les programmes de DP assistée ont été développés pour proposer cette modalité de dialyse aux patients qui ne sont pas capables d'effectuer les manipulations seuls [11,56-67]. De ce fait, la plupart des programmes de dialyse péritonéale sont orientés vers les patients âgés [11,56-60] et une assistance par un tiers peut être proposée. En dialyse péritonéale assistée, selon les systèmes de santé, l'assistance peut être fournie au domicile du patient ou dans un centre de soins, par un employé, un technicien de la santé, une infirmière, ou le conjoint ou un membre de la famille [68].

En France, l'assistance par une infirmière au domicile du patient est autorisée et pris en charge à 100% par l'assurance maladie [69,70]. La DP assistée est utilisée en France depuis de nombreuses années [56,69] quelle que soit la modalité, DPCA ou DPA, et elle est très utilisée chez les patients âgés [11,70,71]. La DP est le traitement choisi par les patients âgés lorsqu'ils ont bénéficié d'une information sur les différentes options possibles [58,72]. Une étude récente de notre équipe a montré qu'il n'existait pas de différence dans la survie de la technique selon la modalité, DPA et DPCA lorsque le patient est assisté [73]. De plus, le risque d'infection péritonéale est similaire entre la DPA assistée ou la DPCA assistée [74].

La capacité d'autonomie du patient est évaluée par l'équipe infirmière de DP. La prescription du néphrologue est utilisée par des infirmières libérales en charge de l'assistance du patient à domicile pour faire une demande de paiement auprès de l'assurance maladie [11].

Le néphrologue en charge du patient doit également confirmer l'assistance familiale ou l'autonomie du patient, puisque que l'assurance-maladie indemnise toutes les personnes traitées par dialyse à domicile (à l'exception de celles assistées par une infirmière).

L'attribution d'une assistance par une infirmière peut être temporaire, pour permettre au patient de prendre confiance en lui et/ou pour soulager le patient et sa famille du poids du fardeau de la maladie

[75]. C'est le patient qui choisit les infirmiers libéraux qui interviendront à son domicile en fonction de son secteur d'habitation. Ceux-ci doivent avoir bénéficié d'une formation par l'équipe de dialyse péritonéale.

Dans une étude de survie, utilisant la méthode des risques compétitifs, Lobbedez et al ont montré que, comparé aux patients autonomes, les patients assistés ont un risque moins élevé d'échec de technique [76]. L'assistance par un infirmier à domicile est associée à un risque moins élevé de péritonite chez les patients âgés [77] et chez les patients diabétiques [78].

Il existe une hétérogénéité d'utilisation de la DP assistée dans le monde conditionnée par le fonctionnement des systèmes de santé [61,79] et tous les pays ne proposent pas la même offre (*tableau 2*). La formation proposée aux aidants est elle-même disparate. En effet, hormis l'assistance par un membre de la famille, l'intervention d'une tierce personne nécessite un financement [80].

Tableau 2. La dialyse péritonéale assistée dans le monde [61,79]

Pays	Modalité d'assistance	Modalité de DP	Déroulement de la formation	Particularités
Canada (On, CB)	Infirmière	DPCA ou DPA	ND	Communication téléphonique entre aidants et centre

Danemark	Infirmière	DPCA ou DPA	2.5 heures de théorie dans le centre 2.5 heures de pratique au domicile	Accueil téléphonique 24 heures sur 24, 7 jours sur 7
France	Infirmière	DPCA ou DPA	2 sessions dans le service de néphrologie	Visites à domicile organisées par le centre
Brésil	Infirmière-assistante	DPA	20 heures théorie + pratique	ND
Royayme Uni	Assistante	DPA	ND	ND
Italie	Assistante	DPCA ou DPA	20 heures (5 séances de 4h) théorie + pratique	Envoi d'images et messages via un smartphone
Chine	Assistante	DPCA	20 heures théorie + pratique	Séances de recyclage en groupe périodique animées par une infirmière, des dietéticiens ou médecins
Taiwan	Domestique étrangère	DPCA ou DPA	ND	ND

ND : données non disponibles

2.7. Les caractéristiques des centres

Les caractéristiques des patients sont utiles pour identifier les sujets ayant un risque d'échec de la dialyse péritonéale et donc transférés en HD, mais ce ne sont pas des facteurs modifiables. En revanche, les caractéristiques des centres dans lesquels sont traités les patients peuvent être modifiables.

Il semble ainsi intéressant d'étudier l'impact des organisations, des composantes des centres, ou des pratiques sur la survenue d'évènements en DP. Ceci afin d'identifier des facteurs modifiables pouvant améliorer le devenir du patient traité par la dialyse péritonéale.

2.7.1. Le type de centre

En France, les patients peuvent bénéficier du traitement par dialyse péritonéale dans un hôpital public (Centre Hospitalier Universitaire ou Centre Hospitalier), un centre de dialyse à but non lucratif ou dans une clinique privée [69, 81]. La dialyse à domicile est généralement sous la responsabilité des associations de dialyse à but non lucratif. De ce fait, les services de néphrologie des hôpitaux proposent la DP aux patients, les néphrologues doivent ensuite transférer leurs patients dans les associations du domicile. Le fait que le centre adresseur perde le forfait correspondant au traitement du patient pourrait constituer un frein au développement de la DP. Les structures publiques et les associations collaborent étroitement pour assurer la prise en charge du patient. Un forfait hebdomadaire de 56 euros est versé pour la prise en charge d'un patient en DP aux néphrologues libéraux ou aux établissements privés les employant.

Chaque établissement de santé en charge de la DP, installe, au domicile du patient l'équipement nécessaire. Il fournit, les dispositifs médicaux directement liés à la réalisation de la dialyse péritonéale [10]. Un forfait, différent pour les patients en DPA ou en DPCA, est versé à l'association du domicile.

2.7.2. L'expérience du centre

Il est difficile de mesurer avec précision l'expérience d'un centre. Elle est liée au nombre de patients traités par dialyse péritonéale.

Certaines équipes considèrent la taille du centre comme le nombre de nouveaux patients démarrant la DP par an, et d'autres, comme la proportion de patients en DP parmi la population des dialysés. On peut considérer que la taille du centre est aussi un indicateur de son expérience, puisque le nombre de patients pris en charge par le centre reflète son activité et pas seulement ses moyens.

Plusieurs études ont montré que la taille et l'expérience du centre sont associés à l'échec technique, au décès, et au risque de survenue d'une péritonite [29, 82-91].

En France, être pris en charge dans un centre initiant un traitement par dialyse péritonéale avec plus de 20 nouveaux patients par an était associé à une diminution du risque de transfert précoce en hémodialyse [29]. Dans une étude néerlandaise, l'échec technique était associé au nombre de patients traité dans le centre et à la proportion de patients en DP. Le risque d'échec technique était plus élevé dans les centres ayant moins de 20 patients en DP [82]. Aux Etats Unis, l'échec technique était associé à un nombre de patients en DP pris en charge dans le centre inférieur à 25 [83]. Dans une étude Australienne, une importante variation des taux d'échec technique entre les centres était observée [85]. L'échec technique était moins fréquent dans les centres ayant une proportion de patients en DP supérieure à 29%. La même équipe [88] rapportait que les patients dans un centre ayant une proportion de patients en DP supérieure à 29% avaient une probabilité significativement plus élevée de guérison d'une péritonite, une probabilité plus faible de retrait du cathéter, un risque plus faible de transfert en hémodialyse et un risque plus faible de récidive de péritonite. Une étude réalisée en Australie et en Nouvelle-Zélande rapportait des différences entre les centres de DP dans le respect des bonnes pratiques [92].

2.7.3. L'organisation infirmière et médicale

L'équipe soignante composée d'infirmières formées à la DP peut être commune avec celle de l'unité de formation et de suivi de la dialyse péritonéale.

La loi précise que l'établissement de santé a en charge l'information des patients, leur formation et leur suivi, doit disposer d'un poste infirmier à temps plein pour dix patients traités par la dialyse péritonéale. Il est également précisé que lorsque l'établissement n'assure pas certaines de ces missions, un poste infirmier à temps plein pour vingt patients peut être suffisant [10].

L'organisation des équipes infirmières diffère selon les centres de traitements. Il existe des centres ayant une équipe avec des IDE dédiées, leur temps de travail étant exclusivement consacré à des tâches ou des actes en rapport avec la DP. Certains centres fonctionnent avec une équipe composée

d'infirmières référentes ayant une expertise en DP, le temps de travail n'étant pas exclusivement consacré à la dialyse péritonéale puisque comportant d'autres activité en relation avec la néphrologie. Enfin, d'autres centres ont une équipe mixte avec un (ou) des infirmiers dédiés et des infirmiers référents.

En général, les néphrologues sont « spécialisés » dans une sous-discipline de la néphrologie (DP, hémodialyse, transplantation, néphrologie clinique). Cependant, dans certains centres, il n'existe pas toujours de néphrologues référents ayant une expertise en DP.

Certains centres pratiquent des visites au domicile (VAD) du patient, que le patient soit autonome ou assisté par un membre de la famille ou un infirmier libéral. Ces visites ont pour objectif d'évaluer les compétences des patients, de repérer des erreurs, de faire le lien avec les équipes infirmières intervenant au domicile du patient pour la dialyse péritonéale. Il existe une disparité de pratiques entre les centres concernant les visites au domicile. On observe plusieurs types de visite : visite de pré-installation, d'installation et visites de suivi qui sont parfois combinées.

Dans une étude française, déjà ancienne, il avait été observé un risque plus élevé de péritonite lors que le patient en DPA était assisté par une infirmière à domicile comparativement à un membre de la famille, sauf si des visites à domicile étaient effectuées [74].

Plusieurs études australiennes concernaient l'effet centre ou plusieurs caractéristiques étaient considérées comme des indicateurs de l'organisation et les pratiques [93,94] : au moins une transplantation rénale réalisée pendant la période de l'étude ; la taille du centre définie par le nombre annuel moyen de patients dans le centre ; la proportion de patients en DP estimée à partir de la population des patients dialysés ; l'exposition à la DPA définie comme la proportion de patients en DP exposée au moins une fois à la DPA au cours de la période de l'étude ; la réalisation d'un test d'équilibre péritonéal définie comme la proportion de patients ayant bénéficié d'un test d'équilibre péritonéal au cours des six premiers mois suivant le début du traitement par DP ; l'exposition à l'icodextrine définie

comme la proportion de patients du centre traités au moins une fois avec de l'icodextrine . On peut noter que la majorité des indicateurs centres n'était pas modifiables. Dans un travail récent, Nadeau-Fredette et al, en utilisant ces indicateurs, mettait en évidence un effet centre sur le risque de survenue d'un premier épisode de péritonite [94].

2.8. Le Registre de Dialyse Péritonéale de Langue Française

Le Registre de Dialyse Péritonéale de Langue Française (RDPLF) est une association à but non lucratif. Il a été officiellement créé en 1988 avec un recueil de données ayant débuté dès 1986 [71]. Des pays francophones participent également à ce registre. En France, 82% des patients en DP sont enregistrés dans le RDPLF. Il a pour objectif de recueillir les caractéristiques des patients mais également aider les équipes à évaluer et améliorer la qualité des soins. Les centres, dont la participation est gratuite et volontaire, fournissent des informations exhaustives sur leurs patients tous les 3 mois.

La base de données est structurée en plusieurs modules liés entre eux, chacun couvrant différents aspects de la DP. Seul le module principal est obligatoire pour les centres souhaitant participer, les autres étant facultatifs : anémie, cathéter, nutrition et dialyse adéquate, cœur.

Le RDPLF comprend aussi un module infirmier. Parmi les 154 centres participants, 125 centres collectent des données pour ce module. L'infirmière responsable du patient enregistre les données individuelles avant le début de la dialyse péritonéale et à la fin du processus de formation. Le module infirmier contient des informations sur la capacité du patient à être autonome et sur les motifs d'incapacités.

3. Méthodologie de l'effet centre

3.1. Approche statistique

Les patients traités dans un même centre de dialyse péritonéale partagent les mêmes caractéristiques. On considère que les données sont structurées selon plusieurs niveaux qui doivent être prises en compte au cours de l'analyse statistique. Les modèles multiniveaux permettent d'analyser des données structurées. L'approche hiérarchique permet de quantifier l'effet centre sur un évènement d'intérêt et d'estimer si des variables centres expliquent l'hétérogénéité entre les centres.

Ces modèles sont très utilisés en épidémiologie parce qu'ils permettent une analyse contextuelle et ainsi d'identifier des populations à risque. Par exemple les individus (niveau 1) d'un même quartier (niveau 2) partagent un environnement commun. L'utilisation d'un modèle hiérarchique permet la prise en compte de ce facteur environnement, de détecter éventuellement des populations à risque et proposer des programmes de santé adaptés [95,96].

Dans nos travaux portant sur l'effet centre, nous avons utilisé une modélisation hiérarchique. Dans les modèles multiniveaux que nous avons utilisés, les variables des patients sont des variables de niveau 1, alors que les variables centres sont les variables de niveau 2. Nous n'avons pas, dans nos travaux, utilisé de variables de niveau 3 pouvant par exemple être des variables du département ou de la région. Schématiquement l'analyse hiérarchique permet d'estimer s'il existe un effet centre sur l'événement d'intérêt, de le quantifier, d'estimer la part de l'effet centre liée aux variables patients et de mettre en évidence des variables centres réduisant l'effet centre. En résumé, on étudie la variabilité individuelle des patients et la variabilité inter-centre de la probabilité de survenue d'un évènement.

3.2. Méthodologie

La méthodologie de l'analyse multiniveau comporte 4 étapes successives.

Sélection des variables

Pour sélectionner les variables pour l'analyse multivarié un modèle statistique sans effet aléatoire est utilisé pour étudier l'association entre les différentes variables et l'évènement d'intérêt.

Détection d'un effet centre (Modèle 0)

Cette étape détermine la poursuite de l'analyse statistique avec un modèle hiérarchique. En effet, il s'agit de vérifier si l'effet centre existe avant de tenter de l'expliquer. Premièrement, un modèle vide est construit (Modèle 0), c'est-à-dire sans aucune variable explicative, avec le centre (niveau 2) en effet aléatoire. Ensuite, le modèle comportant une variance aléatoire (VA) est comparé au modèle vide sans effet aléatoire, avec un test de vraisemblance afin d'estimer la significativité statistique de l'effet aléatoire.

Le coefficient de corrélation intraclasse (CCI) représente la part de la variance totale (c'est-à-dire la variabilité) de l'évènement expliqué par l'effet centre (« random effect » des anglosaxons). Il ne dépend pas de la prévalence de l'événement. Le coefficient est calculé différemment suivant le type de régression utilisée [97]. Par exemple, dans un modèle logistique multiniveaux, le CCI est calculé par la méthode de la variable latente avec la formule suivante [98-100] : $CCI=VA/(VA+\pi^2/3)$ où VA est la variance de l'effet aléatoire et $\pi^2/3$ est la variance de l'erreur logistique standard sous-jacente

Introduction des variables individuelles (Modèle 1)

On modélise l'événement d'intérêt à l'aide d'un modèle de régression mixte avec le centre de traitement en effet aléatoire et les variables individuelles (dites variables de niveau 1). On calcule la modification de la variance aléatoire du modèle vide (modèle 0) résultant de l'introduction dans le modèle 1 des variables patients grâce à la variation proportionnelle de la variance (VPV), **VPV = (VN0-VN1)/VN0,** où VN0 est la variance aléatoire du modèle 0 et VN1 la variance aléatoire du Modèle 1.

Si la VPV augmente ou n'est pas modifiée, on peut en déduire que les caractéristiques individuelles n'expliquent pas l'effet centre.

Introduction des variables centres (modèle 2)

Enfin, les variables centres (dites de niveau 2) sont inclues dans le modèle afin de déterminer si, après un ajustement sur les variables individuelles, la variance aléatoire est modifiée par les variables centres. La variance du modèle 2 est comparée statistiquement à celle du modèle 1. Le CCI et la VPV sont ensuite calculés pour ce modèle 2.

4. Objectifs de la thèse

L'objectif principal de nos travaux était de déterminer s'il existait un effet centre sur la probabilité de survenue d'un événement d'intérêt en dialyse péritonéale puis d'identifier des variables centres modifiables associées à l'événement d'intérêt et réduisant l'effet centre. Cette approche devant permettre aux néphrologues et aux infirmières d'effectuer des modifications au niveau du centre pour améliorer la prise en charge et le devenir du patient traité par dialyse péritonéale. Pour la réalisation de nos travaux nous avons utilisé la modélisation hiérarchique avec le centre en effet aléatoire.

Nos travaux étaient effectués à partir des données du Registre de Dialyse Péritonéale de Langue Française. Une collection de données complémentaires au niveau des centres de traitement était réalisée dans l'objectif d'étudier les caractéristiques et l'organisation des centres de traitement.

5. Echec précoce et effet centre

5.1. Objectif

L'objectif de notre étude était d'évaluer l'importance de l'effet centre sur l'échec précoce, défini par un transfert en hémodialyse dans les 6 premiers mois de la dialyse péritonéale, et d'identifier les organisations propres aux centres associées au risque de transfert précoce en hémodialyse.

5.2. Principaux résultats

Caractéristiques des patients (niveau 1)

Sur les 5 406 patients, 415 avaient arrêté la DP au cours des 6 premiers mois. L'âge médian était de 70 ans (intervalle interquartile [IIQ] = 55 - 80), l'Index de comorbidité de Charlson médian était de 6 (IIQ : 4 - 8), le sexe ratio (H / F) était de 3 186/2 220, et il y avait 1 735 patients diabétiques (32%). Sur les 5 406 patients, 2 758 ont bénéficié d'une DP assistée (482 assistés par la famille, 2 276 assistés par une infirmière). La péritonite (40), le dysfonctionnement du cathéter (82), l'adéquation de la dialyse (58), les problèmes psychosociaux (47), l'échec de l'ultrafiltration (39), la malnutrition (6) et d'autres maladies liées à la DP (143) ont été les causes de l'arrêt de la DP.

Caractéristiques des centres (niveau 2)

Parmi les 128 centres, il y avait 72 (56%) CHG, 20 (16%) associations, 21 (16%) cliniques privées, 15 (12%) CHU. Sur ces 128 centres, 96 (76%) traitaient moins de 10 nouveaux patients en DP par an.

Les VAD ont été effectuées par 113 centres (88%). Parmi ces 113 centres, 87 (68%) ont effectué une VAD avant le démarrage de la DP, 107 (84%) le jour du démarrage de la DP, 14 (11%) 3 mois après le début de la DP (11%), 22 centres 6 mois après celle-ci (17%).

Il y avait des infirmières référentes dans 87 centres (68%) et des infirmières dédiées dans 31 centres (24%).

Résultats

Il y avait une hétérogénéité significative entre les centres, 3,5% de la variance de la probabilité de l'événement d'intérêt était imputable aux différences entre les centres. Au niveau individuel, les traitements de suppléance avant la DP (hémodialyse et transplantation rénale) et la néphropathie étaient associés à un échec précoce de la DP. A l'échelle du centre, seule l'expérience du centre était associée au risque d'échec de la DP. L'effet centre représentait 52% de la variance totale.

5.3. Utilité des résultats

Bien que l'échec de la technique soit un événement fréquent en DP, il existait peu de données sur l'effet du centre de traitement sur le transfert en HD. La grande majorité des travaux déjà publiés ont utilisé des modèles de régression ne comportant pas d'effet aléatoire. Dans notre travail l'utilisation d'un modèle de régression logistique multiniveaux a permis d'estimer l'importance de l'effet du centre sur le transfert précoce en HD.

Dans notre étude il existait une différence entre les centres, qui n'était pas expliqué par les caractéristiques des patients. Il n'y avait pas d'association entre les variables recueillies pour mesurer l'organisation du centre et le risque d'échec précoce de la DP. Le CCI (3,5% de la variance totale du résultat) ne montrait pas un effet centre important. Néanmoins notre étude ne concernait que l'échec précoce du traitement, on ne peut exclure un effet centre plus important sur la survie à long terme de la méthode de dialyse péritonéale.

L'expérience du centre estimé par le nombre de nouveaux patients débutant le traitement par an était associé au risque d'échec précoce de la DP. L'effet centre n'était pas être entièrement expliqué par l'expérience du centre et par les caractéristiques des patients. Augmenter la taille des centres pourrait avoir un effet bénéfique sur la survie de la méthode de traitement [84].

Notre étude visait à évaluer le risque de transfert vers l'HD. A l'issue de ce travail nous avons voulu étudier l'effet centre sur d'autres évènements pouvant survenir en dialyse péritonéale.

5.4. Publication et communication

Notre travail a fait l'objet d'une publication dans la revue Peritoneal Dialysis International en 2016. Il a été cité dans l'éditorial de T. Moraes et J. Perl, « Center-Centered in a Patient-Centered World? ».

Il a également fait l'objet d'une communication orale au 3rd self-care dialysis meeting à Bruxelles en juin 2016 : "Center effect on early PD failure".

5.5. Article

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ESTIMATION OF THE CENTER EFFECT ON EARLY PERITONEAL DIALYSIS FAILURE: A MULTILEVEL MODELLING APPROACH

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♦ *Introduction:* This study was carried out to investigate the center effect on the risk of peritoneal dialysis (PD) failure within the first 6 months of therapy using a multilevel approach.

♦ *Methods:* This was a retrospective cohort study based on data from the French Language Peritoneal Dialysis Registry. We analyzed 5,406 incident patients starting PD between January 2008 and December 2012 in 128 PD centers. The end of the observation period was December 31, 2013.

♦ *Results:* Of the 5,406 patients, 415 stopped PD within the first 6 months. There was a significant heterogeneity between centers (variance of the random effect: 0.10). Only 3% of the variance of the event of interest was attributable to differences between centers. At the individual level, only treatment before PD (odds ratio [OR]: 1.93 for hemodialysis and OR: 2.29 for renal transplantation) and underlying nephropathy ($p < 0.01$) were associated with early PD failure. At the center level, only center experience was associated (OR: 0.78) with the risk of PD failure. Center effect accounted for 52% of the disparities between centers.

♦ *Conclusion:* Center effect on early PD failure is significant. Center experience is associated with a lower risk of transfer to hemodialysis.

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KEY WORDS: Peritoneal dialysis; center effect; multilevel modelling.

Reducing technique failure is a major objective for nephrologists in charge of peritoneal dialysis (PD) patients. It is well established that many factors can contribute to PD failure (1). Patient characteristics associated with technique failure can be used to predict the risk of transfer to hemodialysis (HD) but are non-modifiable factors. It has been established that center organization, center size, and center experience affect technique survival (2–6). Nevertheless, to estimate whether changes at the center level must be implemented, studies are needed to evaluate the magnitude of the center effect *per se* and to identify which organizations are significantly associated with the risk of technique failure. Furthermore, provision of resources for PD centers should be based on their effect on patient outcome. Center organization requirements have been proposed to ensure the success of PD programs (4). To our knowledge, there is no study available about the magnitude of the center effect on the risk of PD failure. Hierarchical modelling produces an estimate of the center contribution to the risk of the event of interest. Early PD failure leading to a transfer to HD is a frequent event (7,8,9). Early PD failure can be defined as a transfer to HD within the first 6 months of PD, regardless of PD duration during the time period. It is accepted that the causes of early PD cessation are different than the cause of late PD failure. Identification of center characteristics associated with a lower risk of early failure may help nephrologists to implement changes in the center organization. In France, structural organizations differ between PD centers, which could affect the risk of transfer to HD.

This study, based on a multilevel analysis, was carried out to evaluate the magnitude of the center effect on early PD failure. The objective was also to identify center organization associated with the risk of early transfer to HD.

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PATIENTS AND METHODS

STUDY POPULATION

This was a retrospective study using data from the French Language Peritoneal Dialysis Registry (RDPLF). The RDPLF was set up in 1986. In France, 82% of all PD patients are registered in the RDPLF. Participating centers provide information regarding their patients every 3 months. Details about the registry management have been published (10). Patients older than 18 years old starting PD in France between January 1, 2008, and December 31, 2012, were included in the study. The end of the observation period was December 31, 2013, and only patients starting PD were included in the study. From the original dataset, we excluded 13 centers that stopped collecting data regularly during the study period. To conduct a multilevel modelling, we excluded 4 centers having only 1 patient starting PD during the study period. There were 5,406 patients from 128 centers in the final dataset.

DEFINITION OF VARIABLES

Patient characteristics (level 1 covariates) were extracted from the database of the RDPLF. Covariates extracted from

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the registry were gender, comorbidities, diabetes mellitus, and underlying nephropathy, PD modality at dialysis initiation (automated PD [APD] or continuous ambulatory PD [CAPD], assisted PD (family assistance, nurse assistance), starting PD after transplantation failure). To assess patient comorbidities we extracted the Charlson comorbidity score (CCI) from the database, and we calculated the modified CCI by subtracting the age sub-score. Sub-optimal PD initiation was defined by a time spent on HD before PD of less than 1 month (11).

To obtain data about center organization and center characteristics (level 2 covariates), an additional questionnaire was sent to each PD facility. Subsequently, the information about the centers was collected by interviewing the head nurse of each PD center. Covariates used to describe center organization were: full-time nurse (nurses dedicated only to PD), part-time nurse (nurses specialized in PD but also involved in other activities), nephrologists specialized in PD, and home visits by PD nurses. The number of nephrologists and nurses by PD center were also noted. As centers were characterized by the number of incident PD patients per center and per year, no caregiver ratio was calculated to avoid colinearity between these 2 covariates. Centers were also separated by category (academic center, community center, non-profit center, and private center).

STATISTICAL ANALYSIS

Categorical covariates were expressed as frequencies and percentages; continuous covariates were expressed as the median (first and third quartile).

The event of interest was early PD failure, defined by a transfer to HD for more than 2 months within the first 6 months of PD, regardless of PD duration during the time period. Renal transplantation and death during the first 6 months on PD were censored. Fine and Gray survival model with random effect was not available. Estimation of the random effect using a Cox model is controversial. The aim of the study was not to evaluate PD duration during the first 6 months of dialysis. Logistic regression model enables risk estimation at a specific time point. Therefore a mixed logistic model, which provides a robust estimation of the center effect, was used for the statistical analysis. To explore the association between each covariate and the event of interest, a bivariate analysis was performed with a logistic regression model that estimates crude odds ratios (ORs) with their 95% confidence interval (CI). Covariates were selected for the multivariate analysis when the *p* value was lower than 0.20 in the bivariate analysis. Variance inflation factor was utilized to assess whether there was colinearity between 2 covariates.

In order to take into account hierarchical data, a multilevel modelling approach was used for the multivariate analysis. A logistic regression modelling was performed with center as a random effect, patient characteristics (level 1), center organizations, and center characteristics (level 2) as fixed effects (12). To detect heterogeneity between centers, we set up an empty model (model 0), with only center as a random effect. Model 0 was compared with a traditional logistic empty model by the likelihood ratio test that was considered to be significant if the *p* value was below 0.05. To quantify the heterogeneity between centers, we calculated the intraclass correlation coefficient (ICC) also called variance partition coefficient (VPC). Intraclass correlation coefficient represents the proportion of the total variance of the outcome attributed to the center level. Intraclass correlation coefficient was estimated with the latent variable method, that is $ICC=VA/(VA+\pi^2/3)$, where VA is the variance of the random effect and $\pi^2/3$ is the variance of the underlying standard logistic error (13). Thereafter, individual covariates (level 1) were included in the model (model 1) to investigate whether center heterogeneity was explained by the patient composition of the center. Subsequently, center covariates (level 2) were included in the model (model 2) to investigate whether center effect was influenced by center characteristics and organization. Model 1 was compared with model 2 by analysis of variance. To estimate the contribution of the covariates introduced in each model, proportional change in variance (PCV) was calculated [$PCV = (VN1-VN2)/VN1$, where VN1 is the variance of random effect of the empty model and VN2 is the level-2 variance of the model 1 or of the model 2] (14).

Statistical analyses were performed with R 3.1.2. (R Foundation for Statistical Computing, Vienna, Austria) including the lme4 package.

The RDPLF has the approval of the French national ethics committee ("Commission Nationale de l'Informatique et des Libertés"). This study took place within the framework of this authorization.

MISSING DATA

The rate of missing data was inferior to 15% for each covariate of the dataset; a multiple imputation by chained equation was performed for all missing data.

RESULTS

PATIENT CHARACTERISTICS

Of the 5,406 patients, 415 stopped PD and transferred to HD within the first 6 months of PD. The median age was 70 years (interquartile range [IQR] = 55 – 80), the median CCI was 6 (IQR: 4 – 8), the gender ratio (M/F) was 3,186/2,220, and there were 1,735 diabetic patients (32%). Of the 5,406 patients, 2,758 were on assisted PD (family-assisted: 482, nurse-assisted: 2,276). Causes of PD cessation were peritonitis (40), catheter dysfunction (82), dialysis adequacy (58), psychosocial problems (47), ultrafiltration failure (39), malnutrition (6), and other related to PD (143). Patient characteristics are presented in Table 1.

CENTER CHARACTERISTICS

Among the 128 centers, there were 72 (56%) community hospital centers, 20 (16%) non-profit centers, 21 (16%)

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private centers, and 15 (12%) academic centers. Of these 128 centers, 97 (76%) treated less than 10 new PD patients per year. Nurse home visits were performed by 113 (88%) centers. Among those 113 centers, 87 (68%) provided a home visit before PD start, 107 (84%) at PD initiation, 14 (11%) 3 months after PD initiation (11%), and 22 centers 6 months after PD initiation (17%). There were part-time nurses in 87 centers (68%) and full-time nurses in 31 centers (24%). Center characteristics are presented in Table 2.

TABLE 1
Patient Characteristics

Covariate	*N*=5,406 No early failure *N*=4,991 Median (IQR)		Early failure *N*=415 Median (IQR)	
Age at PD initiation	70 (55–80)		69 (51–80)	
CCI	6 (4–8)		6 (3–8)	
Modified CCI	3 (2–5)		3 (2–5)	
	N	%	N	%
Age by tertiles				
18–60 years	1,638	33%	144	35%
60–77 years	1,659	33%	125	30%
>77 years	1,693	34%	145	35%
Modified CCI by category				
2	643	13%	71	17%
3	462	9%	38	9%
4	409	8%	33	8%
5	515	10%	36	9%
6	694	14%	65	16%
≥7	2,268	45%	172	41%
Gender (male)	2,935	59%	251	60%
Diabetes	1,606	32%	129	31%
Underlying nephropathy				
Unknown	534	11%	33	8%
Interstitial nephritis	258	5%	26	6%
Glomerulonephritis	737	15%	94	23%
Diabetic	924	19%	74	18%
Polycystic kidney disease	345	7%	24	6%
Miscellaneous	212	4%	13	3%
Uropathy	174	3%	17	4%
Vascular	1,678	34%	115	28%
Systemic disease	129	3%	19	5%
First PD modality (CAPD)	3,792	76%	301	73%
Assisted PD	2,555	51%	203	49%
Modality of assistance				
Self-care PD	2,436	49%	212	51%
Family-assisted PD	448	9%	34	8%
Nurse-assisted PD	2,107	42%	169	41%
Treatment before PD				
Hemodialysis	804	16%	109	26%
Not on dialysis	4,027	81%	279	67%
Renal transplantation	160	3%	27	7%
Suboptimal starter	481	10%	44	11%

IQR = interquartile range; PD = peritoneal dialysis; CCI = Charlson comorbidities index; CAPD = continuous ambulatory PD.

BIVARIATE ANALYSIS

In the bivariate analysis, patient age (OR: 0.94, CI: 0.89 – 0.99), CCI (OR: 0.96, CI: 0.92 – 1.00), and modified CCI (OR: 0.94, CI: 0.89 – 0.99) were associated with a lower risk of early technique failure. There was also a significant association between the underlying nephropathy and the risk of transfer to HD ($p < 0.001$). Patients treated with HD (OR: 1.96, CI: 1.54 – 2.47) or starting PD after transplantation failure (OR: 2.43, CI: 1.56 – 3.66) had a higher risk of transfer to HD. Patients in centers that belonged to the group treating more than 10 new patients per year had a lower risk of early PD failure (OR: 0.71, CI: 0.58 – 0.88). There was no significant relationship between center experience and the causes of early PD failure. There was no association between center category, home visits, full-time nurse, part-time nurse, nephrologists specialized in PD, and transfer to HD. Results of the bivariate analysis are presented in Tables 3 and 4.

TABLE 2
Center Characteristics

Covariate	*N*=128 *N*	%
Center experience (new patients per year)		
<10	97	76%
Type of center		
Non-profit	20	16%
Community hospital	72	56%
Academic hospital	15	12%
Private hospital	21	16%
Home visits		
Home visit	113	88%
Before starting PD	87	68%
At PD initiation	107	84%
3 months after PD initiation	14	11%
6 months after PD initiation	22	17%
Annually	29	23%
Center organization		
Full-time nurses	31	24%
Part-time nurses	87	68%
Other	10	8%
Nephrologists specialized in PD	82	64%
	Median (IQR)	
Number of caregivers		
Numbers of nurses by center	3 (3–5)	
Number of nephrologists by center	5 (3.5–7)	

PD = peritoneal dialysis; IQR = interquartile range.

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MULTILEVEL ANALYSIS

Variance of the random effect was 0.10 and there was a significant variation across PD centers (Table 5). The ICC was 0.03 showing that only 3% of the variance of the event of interest was attributable to differences between centers.

At the individual level (level 1), only treatment before PD (OR: 1.93, CI: 1.69 – 2.17 for hemodialysis and OR: 2.29, CI: 1.84 – 2.74 for renal transplantation) and underlying nephropathy were associated with early PD failure. Variance of the random effect increased by 0.01% after adjustment on patient characteristics. In other words, center effect was not due to differences in the patient characteristics between centers.

At the center level (level 2), only center experience was associated with the risk of PD failure. Variance of the random effect decreased by 52% after adjustment for patient characteristics, center organization, and center experience. That meant that center effect accounted for 52% of the disparities between centers.

TABLE 3
Association Between Each Covariate Patient and Early PD Failure[a]

Covariate	Early failure OR (95% CI)	*p* value*
Age at PD initiation	0.99 (0.99–1.00)	<0.05
Age by decade	0.94 (0.89–0.99)	<0.05
Gender (male)	1.07 (0.87–1.32)	0.5
Diabetes	1.05 (0.85–1.31)	0.87
CCI (per unit)	0.96 (0.92–1.00)	<0.05
Modified CCI (per unit)	0.94 (0.89–0.99)	<0.05
Modified CCI (by category)		
2	Ref	
3	0.74 (0.49–1.12)	
4	0.73 (0.47–1.12)	0.15
5	0.63 (0.41–0.95)	
6	0.85 (0.59–1.21)	
≥7	0.67(0.52–0.92)	
Underlying nephropathy		
Polycystic kidney disease	Ref	
Unknown	0.89 (0.52–1.54)	
Interstitial nephritis	1.45 (0.81–2.59)	
Glomerulonephritis	1.83 (1.17–2.98)	
Diabetes	1.15 (0.73–1.89)	<0.001
Miscellaneous	0.88 (0.43–1.74)	
Urologic	1.40 (0.72–2.67)	
Vascular	0.98 (0.64–1.59)	
Systemic disease	2.12 (1.11–3.99)	
First PD modality (CAPD)	0.83 (0.67–1.05)	0.12
Suboptimal starter	1.11 (0.79–1.52)	0.52
Modality of assistance		
Self peritoneal dialysis	Ref	
Family-assisted	0.87 (059–1.25)	0.64
Nurse-assisted	0.92 (0.75–1.14)	
Treatment before PD		
Not on dialysis	Ref	
Hemodialysis	1.96 (1.54–2.47)	<0.001
Renal transplantation	2.43 (1.56–3.66)	

PD = peritoneal dialysis; OR = odds ratio; CI = confidence interval; CCI = Charlson comorbidities index; CAPD = continuous ambulatory PD.
[a] Bivariate analysis with logistic regression model.
* p-heterogeneity, probability for heterogeneity for non-categorical variables; p-trend: probability for linear tendency for categorical variables.

DISCUSSION

Although technique failure is a frequent event in PD, there are limited data about center effect on transfer to HD. Center effect should be investigated as it would allow modifications at the center level that could improve technique survival. To our knowledge, the studies available about center effect have utilized traditional measures of association between the event of interest and center size (3,5,6). Traditional regression

TABLE 4
Association Between Each Covariate Center and Early PD Failure

Covariate	Early failure OR (95% CI)	*p* value*
Center experience (new patients per year)		
≤10	Ref	<0.01
>10	0.71 (0.58–0.88)	
Type of center		
Non-profit	Ref	
Community hospital	1.18 (0.89–1.59)	
Academic hospital	0.98 (0.69–1.40)	0.50
Private hospital	1.00 (0.62–1.59)	
Home visits		
Home visit	1.13 (0.80–1.64)	0.51
Before starting PD	1.09 (0.88-1.36)	0.42
At PD initiation	1.17 (0.87–1.60)	0.31
3 months after PD initiation	0.88 (0.65–1.18)	0.41
Center organization		
Other	Ref	<0.05
Full-time nurses	1.16 (0.78–1.80)	
Part-time nurses	1.52(1.04–2.30)	
Nephrologists specialized in PD	0.96 (0.78–1.18)	0.68
Number of caregivers		
Number of part-time nurses (organization with part-time nurses)	1.01 (0.97–1.06)	0.46
Number of full-time nurses (organization with full-time nurses)	0.94 (0.89–0.98)	<0.05
Number of nephrologists by center	1.00 (0.98–1.03)	0.45

PD = peritoneal dialysi; OR = odds ratio; CI = confidence interval.
[a] Bivariate analysis with logistic regression model.
* p-heterogeneity, probability for heterogeneity for non-categorical variables; p-trend: probability for linear tendency for categorical variables.

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analysis provides estimates, such as an odds ratio or hazard ratio, which measure the link between center characteristics and the probability of the event of interest. Multilevel logistic regression considers that individual probability of the event of interest is also dependent on the PD center where patients are treated (15). Intraclass coefficient correlation, estimated

TABLE 5
Multivariate Mixed Logistic Regression of Factors Associated with Early PD Failure

Fixed effects	Empty model	Early failure Model 1 OR (95% CI) *p* value*	Model 2 OR (95% CI) *p* value*
Level 1: patients			
Age by decade	–	1.03 (0.96–1.09) 0.41	1.02 (0.95–1.09) 0.57
Modified CCI (per unit)	–	0.95 (0.88–1.01) 0.12	0.95 (0.89–1.02) 0.16
Underlying nephropathy			
Polycystic kidney disease		Ref	Ref
Unknown		1.74 (1.20–2.29)	1.72 (1.18–2.27)
Interstitial nephritis		2.06 (1.64–2.49)	2.04 (1.62–2.47)
Glomerulonephritis		1.55 (1.10–1.99)	1.53 (1.08–1.97)
Diabetes	–	1.17 (0.62-1.73)	1.16 (0.61–1.72)
Miscellaneous		0.93 (0.26–1.60)	0.92 (0.25–1.60)
Urologic		1.56 (0.93–2.19)	1.51 (0.88–2.14)
Vascular		1.19 (0.78–1.60)	1.18 (0.78–1.59)
Systemic disease		2.39 (1.77–3.00) <0.01	2.39 (1.78–3.00) <0.01
First modality (CAPD)	–	0.91 (0.66–1.53) 0.44	0.90 (0.66–1.14) 0.41
Treatment before PD			
Not on dialysis		Ref	Ref
Hemodialysis	–	1.95 (1.71–2.20)	1.93 (1.69–2.17)
Renal transplantation		2.35 (1.79–2.68) <0.001	2.29 (1.84–2.74) <0.001
Level 2: centers			
Center experience (new patients per year)			
≤10	–	–	Ref
>10			0.78 (0.53–1.00) <0.05
Center organization			
Other			Ref
Full-time nurses	–	–	1.17 (0.71–1.63)
Part-time nurses			1.44 (1.00–1.88) 0.11
Random effects			
Level 2: variance (SD)	0.102 (0.319)	0.103 (0.321)	0.049 (0.223)
LRT *p*	<0.05	–	–
Anova *p*	–	<0.001	<0.01
ICC	0.03	0.037	0.01
PCV	Ref	-0.01%	52%

PD = peritoneal dialysi; OR = odds ratio; CI = confidence interval; CCI = Charlson comorbidities index; CAPD = continuous ambulatory PD; SD = standard deviation; LRT = likelihood ratio test; ICC = intraclass coefficient correlation; PCV = proportional change in variance.
* p-heterogeneity, probability for heterogeneity for non-categorical variables; p-trend: probability for linear tendency for categorical variables.

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by the latent variable method, can provide an estimation of the magnitude of the center effect on the outcome of interest (15,16). Intraclass coefficient correlation does not depend on the event prevalence. Our study showed that there was significant heterogeneity between centers. However, the ICC estimation showed that only 3.5% of the total variance of the outcome could be attributed to the center level. In view of the proportional change in variance after adjustment for patient level covariates, heterogeneity between centers could not be explained by differences in patient characteristics between centers. The multivariate analysis showed that underlying nephropathy and treatment before PD were associated with the risk of early transfer to PD. These findings confirmed the results of a previous study about early failure of PD from our group that took into account competing events (6). The final model showed that the effect of the PD center cannot be fully explained by center experience and by patient characteristics. These results suggest that center practice may partially explain early transfer to HD. In support of this, one recent study has documented that training patterns were associated with peritonitis incidence (17). A negative correlation between nurse experience and the risk of gram-positive peritonitis was documented in a study from Hong Kong (18). As peritonitis is one of the leading causes of PD failure, these findings suggest that center experience and practice could affect technique survival.

Nephrologist experience with PD may also partially explain center effect. Among 91 French nephrologists who were asked to give their opinion about the optimal rate of PD, 23% felt that limited training and experience about PD was a barrier to PD development (19). Until recently, there was no core curriculum for PD in French academic hospitals. Only center experience was associated with a lower risk of transfer to HD in our study. This finding is consistent with the results of other studies. In Canada, center experience, measured by the cumulative number of patients treated by PD and the proportion of end-stage renal disease patients treated by PD was a predictor of technique failure (20). Huisman *et al.*, in the Netherlands, found that patients treated in centers with less than 20 patients on PD had a higher risk of transfer to HD (2). In 1 study from the United States, technique failure was higher in centers caring for less than 25 patients (3). Patients treated in PD centers initiating PD in less than 10 patients per year had a greater risk of technique failure in studies taking into account competing risks (6,7). None of these studies have evaluated the magnitude of the center effect or the potential role of center characteristics on technique failure. Surprisingly, there was no link between center organization and the risk of early PD failure in our study. Because our study has only focused on the transfer to HD within the first 6 months of renal replacement, one cannot exclude an effect of center organization on technique survival.

In addition, the aim of our study was to evaluate the risk of transfer to HD; it is obvious that there are other events that may occur on PD, which could be influenced by center organization. As an example, it has been demonstrated that, in France, nurse home visits are associated with a lower risk of peritonitis in patients treated by nurse-assisted PD (21). It has been suggested recently that assessing and training patients at home could improve patients' knowledge (22). Furthermore, nurse-assisted PD patients had a lower risk of PD failure in 1 study from France (7). In France, there are differences between centers in assisted PD utilization, meaning that center practice could impact technique survival (unpublished data). Assisted-PD patients had a similar risk of early peritoneal failure in our study, which finding is in line with a recent study from our group (6).

Our study has several limitations. There were residual confounders, such as body mass index (BMI) or detailed PD prescription, not captured in the registry. In addition, one may argue that differences between centers regarding PD catheter insertion technique could influence PD success. Nevertheless, in France, the vast majority of PD catheters are placed by surgeons under laparotomy (2,409/2,731 PD catheters inserted during the study period – unpublished data from the "catheter section" of the RDPLF).

In conclusion, there is a significant center effect on the probability of early transfer of PD patients to HD. Among center characteristics, only center experience was associated with the risk of PD failure. Further studies are needed to estimate the center effect on other events that may occur during PD.

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6. Péritonite et effet centre

6.1. Objectif

L'objectif de notre travail était de déterminer, en utilisant un modèle de survie multiniveau, s'il existait un effet centre sur la survenue d'un premier épisode d'infection péritonéale, si des variables centres modifiables étaient associées au risque de péritonite et si les variables centres réduisaient l'effet centre.

6.2. Principaux résultats

Caractéristiques des patients

Parmi les 5017 patients, 1796 avaient au moins eu une péritonite. L'incidence de la péritonite était de 2,80 (IC à 95% : 2,70–2,90) par 100 mois-patients en DP. Au cours de la période d'étude, 1385 patients ont été transférés en hémodialyse, 953 patients recevaient une transplantation et il y avait 1690 décès.

L'âge médian au début de la dialyse était de 70 ans [interquartile (IIQ) : 55–80] et l'Index de comorbidité de Charlson modifié médian était de 3 (IIQ) : 2–5]. Le sex-ratio (homme / femme) était de 2986/2031 et il y avait 1614 patients diabétiques (32%). Parmi les 5017 patients, 2570 étaient en DP assisté (famille : 443 ; infirmière : 2127).

Caractéristiques des centres

Parmi les 127 centres, il y avait 69 (56%) CHG, 20 (16%) associations, 19 (16%) cliniques privées, 15 (12%) CHU. Sur ces 127 centres, 96 (76%) traitaient moins de 10 nouveaux patients en DP par an. 113 centres (88%) effectuaient des VAD.

Parmi ces 113 centres, 87 (68%) effectuaient une VAD avant le démarrage de la DP, 107 (84%) le jour du démarrage de la DP, 14 (11%) 3 mois après le début de la DP (11%), 22 centres (17%) 6 mois après celle-ci. Il y avait des infirmières dédiées dans 31 centres (24%).

Résultats

Il y avait une hétérogénéité significative entre les centres dans le risque de survenue d'une première infection péritonéale (variance de l'effet aléatoire : 0,11). 14 centres avaient un hazard ratio [HR] de péritonite supérieur à 1,39 comparativement à la moyenne des centres. La variance de l'effet centre était réduite de 9% après ajustement avec les caractéristiques des patients et de 35% après ajustement sur les caractéristiques centre. Les patients qui étaient traités dans des centres avec une infirmière dédiée ou dans des centres réalisant des VAD avant l'initiation de la dialyse avaient un risque moins élevé de péritonite.

Ni le type de centre ni l'expérience du centre n'influençaient le risque de péritonite. Dans l'analyse en risques compétitifs, les patients traités dans un centre avec des infirmières dédiées à la dialyse péritonéale ou dans un centre réalisant des visites à domicile avait un risque plus faible de péritonite comparativement aux autres sujets.

Les patients traités dans un centre avec un néphrologue référent en DP avaient un risque similaire d'infection péritonéale en comparaison aux autres patients.

6.3. Utilité des résultats

Notre étude a souligné l'importance de l'effet centre sur le risque de péritonite et l'importance de l'infirmière dédiée sur le devenir des patients en dialyse péritonéale.

La plupart des études sur l'effet centre se sont intéressés à la relation entre la taille du centre et la survie de la technique de dialyse ou à la mortalité.

Dans une étude australienne, il était démontré que des variables centre étaient associées à un risque accru de péritonite, cependant les variables centres n'étaient pas modifiables [94]. L'effet bénéfique des mesures préventives de la péritonite en DP pourrait être masqué par un effet centre [101].

Les différences dans les pratiques de formation entre les centres pourraient avoir une influence sur le risque de péritonite [43]. En outre, l'expérience infirmière est associée à la probabilité de survenue de péritonite [102]. Il est possible que les infirmières dédiées à la dialyse péritonéale aient une plus grande compétence pour la formation des patients à la dialyse que les infirmières dont une part du temps de travail est dévolue à d'autres activités. L'étude de Figueiredo et al. [43] rapportait que le temps de formation était associé au risque de péritonite. On peut penser que les infirmières dont le temps n'est pas entièrement dédié à la DP pouvaient consacrer moins de temps à l'éducation du patient et/ou qu'elles étaient plus exposées à l'interruption de tâche lors de l'éducation des patients. On peut aussi émettre l'hypothèse que les infirmières dédiées en DP, compte tenu d'une implication plus importante dans l'activité, actualisaient mieux leurs connaissances et utilisaient mieux les recommandations concernant l'éducation à la dialyse péritonéale [103].

La diffusion et l'utilisation des bonnes pratiques dans les centres de traitement est un sujet de préoccupation. Dans une étude australienne, il était observé de grandes différences dans le taux de péritonite entre les centres et une disparité dans l'adhésion aux recommandations des sociétés savantes [92]. Suite à cette publication les programmes d'amélioration de la qualité dans les centres de dialyse péritonéale mis en place en Australie avaient pour conséquence une diminution des taux de péritonite sur une décennie [104]. Les ressources attribuées aux centres de traitement sont aussi un des moyens pour améliorer le devenir des patients traités par la dialyse péritonéale.

L'effet protecteur des visites à domicile sur le risque de péritonite avait déjà été rapporté par Verger et al. [74]. Une visite à domicile avant le début de la DP est recommandée pour les enfants traités par dialyse à domicile [105]. Chez les enfants la visite à domicile pourrait être associée à une diminution du risque infectieux [106].

Les visites à domicile pourraient aider les patients à débuter le traitement dans leur environnement habituel après la phase de formation en milieu hospitalier. Les visites à domicile, lorsqu'elles sont réalisées avant l'initiation de la dialyse pourraient être un des moyens de sélectionner les patients à plus haut risque d'infection

6.4. Publication et communication

Notre travail a fait l'objet d'une publication dans la revue Nephrology, Dialysis, Transplantation, qui est la revue de l'European Renal Association – European Dialysis and Transplant Association (ERA-EDTA). Il a été cité dans l'éditorial de Y.Cho, H. Htay et DW. Johnson « Centre effects and peritoneal dialysis-related peritonitis ».

6.5. Article

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Original Articles

Centre characteristics associated with the risk of peritonitis in peritoneal dialysis: a hierarchical modelling approach based on the data of the French Language Peritoneal Dialysis Registry

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ABSTRACT

Background. This study investigated the centre effect on the risk of peritonitis in peritoneal dialysis (PD) patients.

Methods. This was a retrospective cohort study based on data from the French Language Peritoneal Dialysis Registry. We analysed 5017 incident patients starting PD between January 2008 and December 2012 in 127 PD centres. The end of the observation period was 1 January 2014. The event of interest was the first peritonitis episode. The analysis was performed with a multilevel Cox model and a Fine and Gray model.

Results. Among the 5017 patients, 3190 peritonitis episodes occurred in 1796 patients. There was significant heterogeneity between centres (variance of the random effect: 0.11). The variance of the centre effect was reduced by 9% after adjusting for patient characteristics and by 35% after adjusting on centre covariate. In the multivariate analysis with a multilevel Cox model, centre with a nurse specialized in PD or centre providing home visits before dialysis initiation decreased the centre effect on peritonitis. Patients treated in centres with a nurse specialized in PD or in centres providing home visits before dialysis initiation had a lower risk of peritonitis [cause-specific hazard ratio (cs-HR): 0.75 (95% confidence interval, CI, 0.67–0.83) and cs-HR: 0.87 (95% CI 0.76–0.97), respectively]. The data show that neither centre type nor centre volume influenced peritonitis risk. In the competing risk analysis, centre with a nurse specialized in PD and centre with home visits had a protective effect on peritonitis [sub-distribution HR (sd-HR): 0.77 (95% CI 0.70–0.85) and sd-HR: 0.85 (95% CI 0.77–0.94), respectively].

Conclusion. There is a significant centre effect on the risk of peritonitis that can be decreased by home visits before dialysis initiation and by the presence of a nurse specialized in PD.

Keywords: centre effect, multilevel modelling, peritoneal dialysis

INTRODUCTION

Peritonitis remains a major concern for peritoneal dialysis (PD) patients and for the nephrologists involved in the care of patients treated by PD. Previous studies have shown that PD infection was associated with peritoneal membrane damage, technique failure and mortality [1–3]. Peritonitis episodes may also affect residual renal function [4]. Recent reports have demonstrated that patients receiving PD were extremely concerned about the risk of peritoneal infection [5]. Furthermore, it is known that peritonitis episodes have a negative effect on the patient's quality of life. The fear of peritonitis also influences the patient's point of view regarding PD when choosing a dialysis modality [6].

There are individual factors such as patient age, diabetes and body mass index that are associated with a higher risk of peritonitis [7–9]. Although these factors are non-modifiable, there are individual factors that also improve peritonitis prevention, since it has been documented that assisted PD, in specific subgroups of patients, could decrease the risk of peritonitis [10, 11]. There are also guidelines and recommendations that have been established to reduce peritonitis incidence [12]. Nevertheless, efforts are needed to implement these recommendations at the centre level. A study from Australia and New Zealand, reported wide

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variations between PD centres in adherence to best practices, which could lead to a centre effect on peritonitis occurrence [13]. A recent study reported the role of the centre effect on the likelihood of peritonitis [14]. Therefore, studies are clearly needed to identify centre-related factors that could explain the role of centre on the chance of peritonitis. The centre effect could be partially explained by the centre experience and/or by the centre practice and/or by the centre organization. Therefore, specific statistical methods must be used to evaluate the impact of centre characteristics, considering the difference between the patients treated in these centres. To our knowledge only one study has evaluated the impact of the centre effect on the peritonitis risk with appropriate statistical methods [14]. However, this study did not include information regarding the role of the centre organization *per se* on the centre effect. It is also important to evaluate whether there are centre characteristics that could decrease the centre effect.

This study was conducted to estimate whether the key points of the organization of the PD centre could explain the centre effect on the peritonitis risk using hierarchical modelling. The main objective was to identify protective factors at the centre level, which could be modified.

MATERIALS AND METHODS

Study population

This was a retrospective study using data from the French Language Peritoneal Dialysis Registry (RDPLF). Patients older than 18 years who began PD in France between 1 January 2008 and 31 December 2012 were included in the study. The end of the observation period was 1 January 2014. Only patients incident on PD were included in the study. From the original data set, we excluded 13 centres that stopped collecting data regularly during the study period. In order to conduct a multilevel modelling, we excluded five centres having fewer than five patients starting PD during the study period. There were 5017 patients from 127 centres in the final data set.

Definition of variables

Individual characteristics (Level 1 covariates). The patient characteristics were extracted from the database of the RDPLF. The following covariates were extracted from the registry: gender, comorbidities, diabetes mellitus, underlying nephropathy, PD modality at dialysis initiation [automated PD (APD) or continuous ambulatory PD (CAPD)], assisted PD (family assistance, nurse assistance) and starting PD after transplantation failure. To assess patient comorbidities, we extracted the Charlson comorbidity score (CCS) from the database and calculated the modified CCI by subtracting the age sub-score.

Centre characteristics (Level 2 covariates). The centres were separated by category (academic centre, community centre, non-profit centre, private centre). Centre experience was estimated by the number of incident PD patients by centre and by year during the study period. The centre experience was dichotomized into two categories based on the results of previous study by our group. We obtained data concerning the centre organization and centre characteristics, using an additional questionnaire sent to each PD facility. The centres' information was collected by interviewing the head nurse of each PD centre. The covariates used to describe the centre organization included the following: at least one full-time nurse specialized in PD (which meant nurse with specific skills on PD, dedicated only to PD and not involved in other activity); at least one nephrologist specialized in PD in the centre (having specific skills on PD but not only involved in PD, which meant the physician referent for PD in the centre); and home visits by nurses from the PD centre before PD, at PD start and 3 and 6 months after PD initiation. The caregiver ratio was calculated by dividing the number of nurses specialized on PD by the number of incident PD patients by centre and by year.

Statistical analysis

The categorical covariates were expressed as frequencies and percentages, and the continuous covariates were expressed as the median with the first and third quartile.

The event of interest was the first peritonitis episode. Renal transplantation and death were censored. A Cox model with centre as random effect was used for the statistical analysis. To explore the association between each covariate and the event of interest, a bivariate analysis was performed with a Cox model to estimate cause-specific hazard ratio (cs-HR) with their 95% confidence interval (CI). For the hierarchical modelling, to improve the assessment of the centre effect, Level 1 covariates were entered in the multivariate analysis *a priori*. Conversely, for the centre characteristics, Level 2 covariates were selected when $P < 0.20$ in the bivariate analysis.

We used an empty Cox model (Model 0), with only centre as a random effect to detect heterogeneity between centres. The variance of the random effect was used to estimate the heterogeneity between centres. Thereafter, individual covariates (Level 1) were included in the Cox model (Model 1) to investigate whether centre heterogeneity was explained by the patient composition of the centre. Subsequently, centre covariates were included in the model (Model 2) to investigate whether the centre effect was influenced by centre characteristics. Model 1 was compared with Model 2 by analysis of variance (ANOVA). To estimate the contribution of the covariates introduced in each model, proportional change in variance (PCV) was calculated.

The random effect coefficient is Gaussian distribution with mean set to zero. Zero is the reference class (the exponential function of the mean is equal to 1). Therefore, the excess risk can be estimated with the exponential of the standard deviation (SD) of the random effect that is a cs-HR with the mean of the random effect as reference class. To express the uncertainty of the estimator, the 95% CI of the cs-HR was estimated by a bootstrapping procedure.

A competing risk analysis (Fine and Gray model), which accounts for the risk of death and renal transplantation before peritonitis, was used to estimate the impact of the centre characteristics on the PD population.

All statistical analyses were performed with R 3.1.2. (R Foundation for Statistical Computing) including the coxme package.

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The RDPLF has the approval of the French national ethics committee 'Commission Nationale de l'Informatique et des Libertés'. This study was conducted within the framework of this authorization.

Missing data

The rate of missing data was <15% for each covariate of the data set; a multiple imputation by chained equation was performed for all missing data.

RESULTS

Patient characteristics

Of the 5017 patients, 1796 subjects had at least one peritonitis event. Peritonitis incidence was 2.80 (95% CI 2.70–2.90) per 100 patient-months on PD. During the study period, 1385 patients were transferred to haemodialysis. Furthermore, 953 patients received transplantation and there were 1690 deaths. The median age at dialysis initiation was 70 years [interquartile range (IQR) = 55–80] and the median modified CCI was 3 (IQR) = 2–5]. The sex ratio (male/female) was 2986/2031, and there were 1614 diabetic patients (32%). Of the 5017 patients, 2570 were on assisted PD (family assisted, 443; nurse assisted, 2127). The patient characteristics are presented in Table 1.

Centre characteristics

Among the 127 centres, there were 69 (56%) community hospital centres, 20 (16%) non-profit centres, 19 (16%) private centres and 15 (12%) academic centres. Of these 127 centres, 96 (76%) treated fewer than 10 new PD patients per year. Home visits by the nurse from the PD unit were performed by 112 (88%) centres. Among those 112 centres, 87 (68%) provided a home visit before PD start, 107 (84%) at PD initiation, 14 (11%) 3 months after PD initiation and 22 (17%) 6 months after PD initiation. There were nurses dedicated only to PD (which were the so-called nurse specialized in PD) in 31 (24%) centres.

Table 1. Patient characteristics

Covariates	n = 5017 patients	(%)
Age at PD initiation, median (IQR)	70 (55–80)	
Modified CCI, median (IQR)	3 (2–5)	
Gender (male)	2986	59
Diabetes	1614	32
Underlying nephropathy		
Unknown	521	11
Interstitial nephritis	265	5
Glomerulonephritis	770	15
Diabetic	929	18
Polycystic kidney disease	343	7
Miscellaneous	202	4
Uropathy	177	3
Vascular	1685	34
Systemic disease	125	2
PD modality at 3 months (CAPD)	3172	76
Modality of assistance		
Self-care PD	2447	49
Family-assisted PD	443	9
Nurse-assisted PD	2127	42
Naive at PD start (not on HD or transplanted)	4249	85
Centre characteristics		
Nurse specialized in PD	2185	43
Nephrologist specialized in PD	3301	66
Home visit before starting PD	3309	66
Home visit at PD initiation	4317	86
Home visit at 3 months	736	14
Home visit at 6 months	1032	20

Values are represented as number and percentages, unless otherwise specified. HD, haemodialysis.

Bivariate analysis

There was no significant relationship between centre experience, centre category and the risk of peritonitis. Home visits by PD nurses were associated with a lower risk of peritonitis [cs-HR: 0.80 (95% CI 0.68–0.92)]. In addition, there was a significant relationship between home visits organization and the risk of peritonitis: home visits before PD initiation [cs-HR: 0.84 (95% CI 0.76–0.93)] and at the start of PD [cs-HR: 0.84 (95% CI 0.76–0.93)] were associated with a lower risk of peritonitis, whereas home visits 3 and 6 months after PD initiation had no protective effect. Specialization of the PD team was also associated with the risk of peritonitis: patients treated in a centre with full-time nurses specialized in PD or a nephrologist specialized in PD had a lower risk of peritoneal infection [cs-HR: 0.75 (95% CI 0.69–0.83) and cs-HR: 0.89 (95% CI 0.81–0.99), respectively]. The results of the bivariate analysis are presented in Tables 2 and 3.

Multivariate analysis

Hierarchical modelling. The SD of the random effect was 0.33 in Model 0. This result indicates that before any adjustment, the patients treated in centres with a random effect greater than 1 SD above the mean had a relative risk of peritonitis (with the mean as reference class) higher than 1.39 (the exponential function of 0.33). There were 14 centres with a risk of peritonitis 1 SD above the mean. The variance of the random effect decreased by 9% after adjusting for patient characteristics and by 35% after adjusting for patient and centre characteristics.

Table 2. Association between patient characteristics and peritonitis (bivariate analysis with Cox regression model)

Covariates	cs-HR (95% CI)	P-value
Age (years)	0.99 (0.99–1.00)	<0.01
Gender (male)	1.04 (0.95–1.15)	0.38
Diabetes	1.14 (1.03–1.25)	<0.01
Underlying nephropathy		
Polycystic kidney disease	Ref	Ref
Unknown	1.07 (0.84–1.34)	0.58
Interstitial nephritis	1.16 (0.88–1.52)	0.29
Glomerulonephritis	1.22 (0.98–1.52)	0.07
Diabetes	1.11 (0.97–1.18)	0.36
Miscellaneous	1.16 (0.86–1.58)	0.33
Urologic	1.47 (1.09–1.98)	0.01
Vascular	1.02 (0.84–1.26)	0.81
Systemic disease	1.22 (0.86–1.74)	0.25
PD modality at 3 months (CAPD)	1.03 (0.94–1.14)	0.47
Modality of assistance		
Self-PD	Ref	Ref
Family-assisted PD	1.02 (0.86–1.21)	0.80
Nurse-assisted PD	0.92 (0.83–1.01)	0.08
Incident on PD	0.95 (0.83–1.08)	0.44

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These results corresponded to a relative risk of 1.29 (estimation based on 1 SD), which is lower than the relative risk observed before the adjustment for the centre characteristics.

Table 3. Association between each centre characteristics and peritonitis (bivariate analysis with Cox regression model)

Covariate	cs-HR (95% CI)	P-value
Centre experience (new patients per year per centre) >10	0.97 (0.88–1.06)	0.51
Type of centre		
Academic centre	Ref	
Private centre	0.91 (0.74–1.11)	0.34
Non-profit centre	0.91 (0.79–1.06)	0.22
Community centre	1.01 (0.90–1.14)	0.82
Home visits organization		
Home visits	0.80 (0.68–0.92)	<0.01
Before starting PD	0.84 (0.76–0.93)	<0.01
At PD initiation	0.81 (0.71–0.92)	<0.01
PD initiation after 3 months	0.95 (0.83–1.09)	0.46
PD initiation after 6 months	0.96 (0.86–1.09)	0.56
Specialization of the PD team		
Nephrologists specialized on PD	0.89 (0.81–0.99)	0.04
Nurse specialized on PD	0.75 (0.69–0.83)	<0.01
Number of nurses specialized on PD by new patients per year	0.37 (0.28–0.51)	<0.01

At the centre level, home visits before PD initiation was associated with a lower risk of peritonitis. However, home visits at PD start had no protective effect. There was also a protective effect of a nurse specialized on PD [cs-HR: 0.75 (95% CI 0.67–0.83)]. Patients treated in-centre by a nephrologist specialized on PD had a similar risk of peritonitis to their counterparts [cs-HR: 0.91 (95% CI 0.80–1.00)]. There were no significant interactions between home visits before dialysis initiation and home visits at the start of dialysis. There were also no interactions between nurses specialized on PD and nephrologists specialized on PD. The results of the multilevel analysis are presented in Table 4.

Fine and Gray modelling. In the multivariate analysis considering the competing risk of death and renal transplantation with a Fine and Gray regression model (data not shown), patients treated in a centre with a nurse specialized on PD, or in a centre with nurse visits before dialysis start had a lower risk of peritonitis [cs-HR: 0.77 (95% CI 0.70–0.85) and sd-HR: 0.85 (95% CI 0.77–0.94), respectively]. The patients treated in a centre with a nephrologist specialized on PD had a similar risk of peritoneal infection to the other patients [sd-HR: 0.98 (95% CI 0.88–1.08)]. The non-adjusted cumulative incidence function of peritonitis is presented in Figures 1 and 2.

Table 4. Hierarchical analysis (multivariate analysis with a mixed Cox model)

	Model 0 Empty model	Model 1 HR (95% CI)	Model 2 HR (95% CI)
Level 1 covariates			
Age (years)	–	0.99 (0.99–1.00)	0.99 (0.99–1.00)
Gender	–	1.05 (0.96–1.17)	1.05 (0.95–1.17)
Diabetes	–	1.34 (1.17–1.59)	1.36 (1.16–1.59)
Modified CCI (unit)	–	1.00 (0.97–1.04)	1.00 (0.98–1.04)
Underlying nephropathy	–		
Polycystic kidney disease		Ref	Ref
Unknown		1.03 (0.81–1.32)	1.03 (0.80–1.31)
Interstitial nephritis		1.15 (0.86–1.51)	1.16 (0.86–1.53)
Glomerulonephritis		1.14 (0.94-–.44)	1.15 (0.94–1.45)
Diabetes		0.84 (0.65–1.09)	0.84 (0.65–1.10)
Miscellaneous		1.05 (0.78–1.36)	1.05 (0.75–1.42)
Urologic		1.29 (0.78–1.36)	1.29 (0.93–1.76)
Vascular		0.99 (0.81–1.23)	0.99 (0.80–1.26)
Systemic disease		1.16 (0.78–1.64)	1.15 (0.77–1.63)
PD modality at 3 months (CAPD)	–	1.10 (0.98–1.24)	1.09 (0.98–1.24)
Modality of assistance	–		
Self-PD		Ref	Ref
Family-assisted PD		1.02 (0.83–1.22)	1.01 (0.84–1.20)
Nurse-assisted PD		0.97 (0.84–1.13)	0.97 (0.85–1.12)
Treatment before PD	–		
Naïve on PD (not on HD or transplanted)		0.99 (0.86–1.16)	0.99 (0.86–1.15)
Level 2 covariates			
Home visits	–	–	
Before starting PD			0.87 (0.76–0.97)
At PD initiation			0.90 (0.78–1.07)
Specialization of the PD team	–	–	
Nephrologists specialized on PD			0.91 (0.80–1.00)
Nurse specialized on PD			0.75 (0.67–0.83)
Random effect			
Standard error (variance)	0.33 (0.11)	0.32 (0.10)	0.26 (0.07)
Standard error of the variance of the random effect	0.06–0.16	0.06–0.16	0.03–0.11
P-value (ANOVA)	–	<0.01	<0.01
PCV (%)	–	9	35

HD, haemodialysis.

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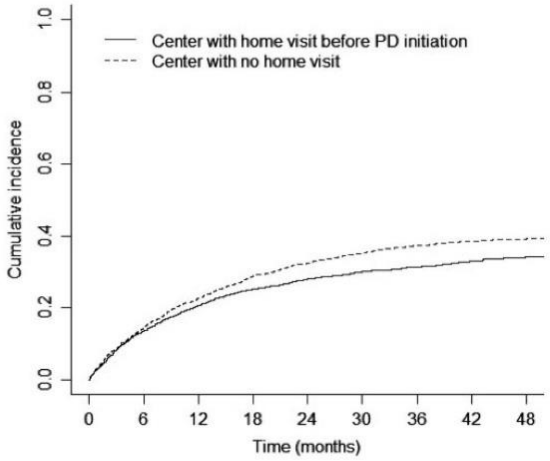

FIGURE 1: Cumulative incidence of peritonitis by centre organization (home visits). Dashed line: centre without home visits by PD nurses before PD initiation; solid line: centre with home visits before peritoneal initiation. Gray test: $P < 0.05$.

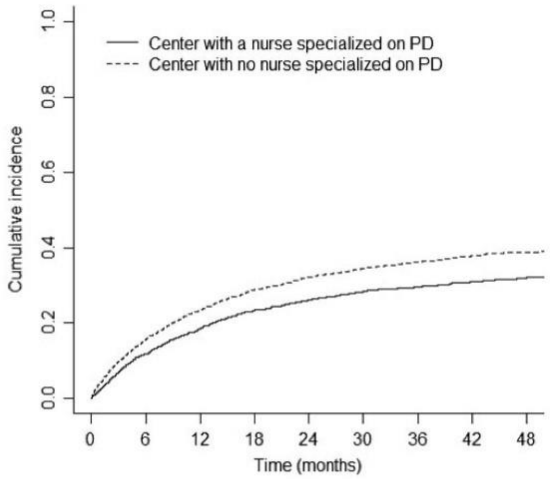

FIGURE 2: Cumulative incidence of peritonitis by centre organization (nurse specialization). Dashed line: centre without a nurse specialized in PD; solid line: centre with a nurse specialized in peritoneal initiation. Gray test: $P < 0.05$.

DISCUSSION

The results of our study are consistent with the findings of a recent investigation conducted in Australia regarding the centre effect on peritonitis risk [14]. In this study, the heterogeneity between centres decreased by 16% when patient characteristics were entered in the multivariate analysis. The heterogeneity decreased by 34% when centres covariates were also included. Studies focused on how centres' effect alter the outcome on PD are clearly needed because factors that could explain the centre effect are potentially modifiable [15, 16]. Most of the studies on the centre effect have investigated the relationship between centre volume and technique survival or mortality [17]. To our knowledge only one report assessed the association between centre characteristics and peritonitis [14]. However, in this study there were unexpected and unclear association between centres' characteristics and peritonitis risks. Furthermore, covariates at the centre level associated with an increased risk of peritonitis were not changeable. It is also important to note that the beneficial effect of preventive measures against peritonitis in PD could be masked by the centre effect [18]. Studies with a hierarchical approach allow for the estimation of the magnitude of the centre effect to identify the measures that should be prioritized at the centre level [19]. Furthermore, the allocation of resources to a PD centre and utilization of these resources in the facility must be based on how they affect patient outcome. In our study, patients treated in a centre with a nurse specialized in PD had a lower risk of peritonitis regardless of the centre size. However, a centre with a nephrologist specialized on PD was marginally associated with peritonitis risk. It is intuitively accepted that patient training is associated with the risk of peritonitis. Thus, differences in training practice between centres could influence the risk of peritonitis [20]. An international survey in PD nurses highlighted the wide variation between centres in PD training programmes [21]. In addition, it has been demonstrated that nurse experience has an impact on the likelihood of peritonitis [22]. Nurses specialized in PD may have greater teaching skills than nurses involved in other activities. The study of Figueiredo *et al.* [20] reported that low training time was associated with a higher risk of peritonitis. Therefore, one may also argue that nurses not fully dedicated to PD and involved in other activities may have less time devoted to patient education and/or are exposed to a higher risk of job interruption when they are performing patient education. It can be hypothesized that nurses specialized in PD are more prone to update their knowledge regarding PD and to use the existing recommendations when teaching the principles of PD [23]. Spreading and utilizing best practices at the centre level is also a matter of concern. In Australia and New Zealand, it has been shown that there were large differences in the peritonitis rate between centres and unexplained wide variation in the adherence to existing recommendations [13]. Although sustained efforts are still necessary to reduce peritoneal infection, in these countries, quality improvement programmes at the PD unit level have led to a dramatic improvement of the peritonitis rate over one decade [24]. Nevertheless, we believe that providing sufficient resources at the centre level that allows dedicated specialized nurses to deliver patient care is required to improve the outcomes of the patients on PD.

In our study, both home visits before starting PD and at PD initiation by nurses from the PD unit were associated with a lower risk of peritonitis in the bivariate analysis. However, the multivariate analysis revealed that only nurse visits before starting PD were associated with a lower likelihood of peritonitis. The beneficial effect of home visits on the peritonitis risk has already been reported by Verger *et al.* [25] in a study examining assisted APD in France. A home visit before PD initiation is recommended in paediatric PD patients [26]. In this specific population, there was a trend towards a protective effect of home visits [27]. The home

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visits could help PD patients to start the treatment correctly at home. Conversely, home visits could also reflect a selection process of patients suitable for PD by the PD unit, especially in centres where home visits are done before the start of PD.

Our study has several limitations as residual confounders, such as body mass index, residual renal function, detailed information about PD prescription and centre practice, are not captured in the registry.

This study confirms the importance of the centre effect on peritonitis risk. Our study also emphasizes the role of nurse specialization and activities in the outcome of patients on PD. In our opinion, health authorities must consider the importance of PD nurses when choosing how to distribute funding.

CONFLICT OF INTEREST STATEMENT

None declared.

(See related article by Cho *et al.* Centre effects and peritoneal dialysis-related peritonitis. *Nephrol Dial Transplant* 2017; 32: 913–915)

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7. Etude de l'attribution d'une assistance en dialyse péritonéale.

7.1. Objectif

La plupart des programmes de DP assistée sont destinés aux patients âgés. Cependant, il existe également des patients plus jeunes incapables d'être autonome en dialyse péritonéale.

Notre étude avait pour objectif d'estimer la prévalence de la dialyse péritonéale assistée dans une population âgée de moins de 65 ans et de déterminer les variables individuelles et les variables centres qui étaient associés à l'attribution de la dialyse péritonéale assistée chez les sujets débutant la dialyse péritonéale en France. L'autre objectif de notre travail était d'estimer l'importance de l'effet centre sur l'attribution de la dialyse péritonéale assistée par une infirmière.

7.2. Principaux résultats

Caractéristiques des patients

Il y avait 2 269 patients âgés de 18 à 65 ans traités dans 127 centres de 77 départements. Parmi ces patients, 114 (5%) utilisaient la DP assistée par la famille et 272 (12%) la DP assistée par une infirmière. L'âge médian était de 51 ans (intervalle interquartile [IIQ]: 40 - 59), l'ICC médian était de 3 (IIQ: 2–5) et le sex-ratio (M / F) était de 1 350/919. Il y avait 480 patients diabétiques (21%). Les patients en DP assistée étaient plus âgés, plus comorbides et plus fréquemment diabétiques que leurs homologues non assistés. Les patients en DP assistée par une infirmière étaient plus fréquemment traités avec la DPCA que les patients aidés par la famille et les patients autonomes.

Caractéristiques des centres

Nous avons utilisé comme caractéristiques des centres les variables centres de nos précédentes études (*cf supra*). Les 127 centres étaient répartis dans 77 départements.

Résultats

L'âge du patient était associé à la probabilité d'être traité par DP assistée par une infirmière et par la famille. Le lien entre l'âge et DP assistée par une infirmière était plus important que le lien entre l'âge et la DP assistée par la famille. Le sexe (femme comme classe de référence) était uniquement associé à la DP assistée par une infirmière. Les comorbidités et la néphropathie étaient associées à la fois à l'assistance par une infirmière et à l'assistance par la famille sans qu'il soit observé de différence statistique entre les deux associations. Les patients traités dans un centre débutant la dialyse péritonéale chez plus de 10 nouveaux patients par an étaient plus fréquemment assistés par une infirmière. Il n'y avait pas d'association entre l'expérience du centre et la DP assistée par la famille. Les patients traités dans des centres avec des infirmières dédiées étaient moins à risque d'être en DP assistée par une infirmière que les autres sujets. Il n'y avait pas d'association statistique entre l'organisation du centre et la DP assistée par la famille. Il n'y avait pas de relation significative entre la catégorie de centre, les centres avec des néphrologues référents en DP et l'utilisation de la DP assistée.

La variance de l'effet aléatoire était de 0,45 témoignant d'une hétérogénéité entre les centres dans l'utilisation de la DP assistée par une infirmière. Au niveau individuel, l'âge, le sexe (femme comme classe de référence), le CCI modifié, la néphropathie et le traitement par HD avant le début de la DP étaient associés à l'utilisation de la DP assistée par une infirmière. La variance de l'effet aléatoire augmentait de 19% après ajustement sur les caractéristiques individuelles, montrant que l'effet centre n'était pas dû aux différences de caractéristiques du patient entre les centres. La variance de l'effet aléatoire et du CCI diminuaient (0,37 et 0,10, respectivement) après l'ajustement sur les variables de niveau 2. Néanmoins, aucune variable centre n'était significativement associée à l'utilisation de la DP assistée par une infirmière.

7.3. Utilité des résultats

Notre travail montre que l'incapacité du patient à être autonome au début de la dialyse est une situation fréquente dans une population non âgée débutant la dialyse.

Il a été démontré que chez les sujets âgés en DP assistée, les troubles fonctionnels sont très fréquents et associés à des comorbidités [107]. Les patients inclus dans notre étude avaient moins de 65 ans, ce qui pourrait être due à un déclin fonctionnel précoce chez les patients en insuffisance rénale.

Nos résultats montrent que les patients traités par hémodialyse avant la dialyse péritonéale avaient une probabilité plus importante d'être traités par DP assistée par une infirmière que les autres patients. Une partie des patients traités par hémodialyse sont pris en charge dans un contexte d'urgence et/ou sans suivi néphrologique préalable. Il est possible que l'assistance par infirmière ait pu servir de passerelle vers la dialyse péritonéale autonome pour les patients débutant la dialyse en hémodialyse puis transféré en dialyse péritonéale. Une étude danoise a souligné que l'utilisation combinée d'un programme de DP non planifiée et assistée permettait aux patients pris en charge tardivement en dialyse d'avoir un choix entre les modalités de dialyse [108]. Une perte d'autonomie pendant le temps passé en hémodialyse pourrait également affecter la capacité du patient à être traité par dialyse péritonéale autonome [109].

Dans notre étude, il y avait une variabilité significative entre les centres dans l'utilisation de la dialyse péritonéale assistée par une infirmière. Cependant, l'expérience et l'organisation du centre n'influençaient ni le taux d'utilisation de la dialyse péritonéale assistée ni les modalités d'assistance. Compte tenu de l'hétérogénéité entre les centres, on ne peut exclure que, dans certains cas, la décision concernant l'aide par des infirmières libérales n'était pas appropriée. Même si la dialyse péritonéale assistée par une infirmière est moins coûteuse que l'hémodialyse en centre, l'assistance d'un patient entraîne des coûts supplémentaires, dans une situation ou l'utilisation des ressources affectées à la santé doit être priorisée [110].

Notre travail montre qu'il existait une hétérogénéité entre les centres dans l'utilisation de l'assistance par une infirmière. Notre prochain travail aura pour objectif de mieux identifier les patients devant être assistés en évaluant la dextérité avec des outils d'ergothérapie.

7.4. Publication et communication

Notre travail a fait l'objet d'une publication dans le journal Nephrology, Dialysis, Transplantation.

Il a aussi fait l'objet de plusieurs communications orales dans des congrès :

- 4th self-care dialysis symposium à Bruxelles en mai 2018 : « Center disparities in the care of PD patients in France »
- Université de la dialyse de la Société Française de Néphrologie, Dialyse et Transplantation à Caen en juin 2018 : « Attribuer une assistance à domicile en dialyse »
- 4mes Journées Francophones de Recherche en Soins à Angers en mai 2018 : « Facteurs associés avec l'assistance par un(e) infirmier(e) libéral(e) chez les patients non âgés traités par dialyse péritonéale »

Enfin, il a été l'objet d'un poster commenté au 13th European Peritoneal Dialysis Meeting à Dublin en mai 2017 : « Factors associated with assisted peritoneal dialysis in non-elderly patients. Data from the French Language Peritoneal Dialysis Registry (RDPLF) ».

7.5. Article

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ORIGINAL ARTICLE

Factors associated with nurse assistance among peritoneal dialysis patients: a cohort study from the French Language Peritoneal Dialysis Registry

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ABSTRACT

Background. No information is available regarding nurse-assisted peritoneal dialysis (PD) in non-elderly subjects. This study was carried out to estimate the rate of nurse-assisted PD among non-elderly patients and to assess which individual and centre factors were associated with nurse-assisted PD. The other objective was to estimate the magnitude of the centre effect on the utilization of nurse-assisted PD using hierarchical modelling.

Methods. This was a retrospective study based on data from the French Language Peritoneal Dialysis Registry. Patients incident on PD > 18 and < 65 years of age were included.

Results. There were 2269 incidents of PD initiation between January 2008 and December 2012 in 127 PD centres with 114 (5%) on family-assisted PD and 272 (12%) on nurse-assisted PD. At the individual level, compared with autonomous patients, nurse assistance was associated with age {odds ratio [OR] 1.79 [95% confidence interval (CI) 1.51–2.13]}, gender [OR 0.47 (95% CI 0.35–0.64)], comorbidities and underlying nephropathy. There was significant heterogeneity between centres in the nurse assistance utilization (variance of random effect 0.12). At the centre level, the type of centre, centre experience, centre organization and private nurse density were not associated with nurse-assisted PD.

Conclusions. The rate of nurse-assisted PD among non-elderly patients was 12%. There was a significant centre effect in the utilization of nurse assistance that was not explained by the centres' characteristics. Nurse-assisted PD utilization in non-elderly patients is associated with patient characteristics and also with centre practices.

Keywords: assisted peritoneal dialysis, centre effect, nursing, peritoneal dialysis

INTRODUCTION

Most of the assisted peritoneal dialysis (PD) programmes are oriented towards elderly patients [1–6]. However, there are also younger patients unable to perform PD. It is widely accepted that a free choice of dialysis modality must be offered to patients reaching end-stage renal disease (ESRD). Accordingly, home therapy should be considered as an option for every dialysis patient. To overcome the barrier of patient incapability, assisted PD programmes have been developed in many countries [7–10]. Assisted PD can be defined as a treatment performed at the patient's home with the assistance of a nurse, a dialysis assistant or a family member [11]. To our knowledge, there are no data available about the use of assisted PD in the non-elderly population. Therefore, studies are needed to identify the rate of assisted PD in this subgroup of patients and the factors associated with its utilization. To our knowledge, apart from one study from Canada, there is no information available in the literature regarding the criteria and tools that could be used to make the decision to assist a PD patient [12] and no guidelines have been established to identify which patients must receive assistance. Therefore, this lack of recommendations raises the question of the heterogeneity of assistance utilization between centres that could reflect the need for a standardized patient capability evaluation. Thus heterogeneity between centres in the utilization of assisted PD must be investigated at a nationwide level.

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This study was carried out to estimate the rate of nurse-assisted PD in the non-elderly PD population and to evaluate which individual and centre factors are associated with the utilization of assisted PD among subjects starting PD in France. The other objective of the study was to estimate the magnitude of the centre effect on the utilization of nurse-assisted PD in the non-elderly population.

MATERIALS AND METHODS

Study population

This was a retrospective study using data from the French Language Peritoneal Dialysis Registry (RDPLF). All cases of PD among incident patients > 18 and < 65 years of age who started PD between 1 January 2008 and 31 December 2012 that were recorded in the RDPLF were included. From the original data set, we excluded 13 centres that stopped collecting data regularly during the study period. In the final data set, there were 2269 patients treated in 127 centres from 77 districts.

Covariate of interest

The covariate of interest was nurse-assisted PD, which was defined as continuous ambulatory peritoneal dialysis (CAPD) or automated peritoneal dialysis (APD) performed by a private nurse at the patient's home at dialysis initiation. Assistance by a family member could be linked to the relationship between the patient and his/her relative and then could be unrelated to the inability to perform PD. Therefore, the study focused on the utilization of nurse assistance.

Patient characteristics (Level 1 covariates)

Patient characteristics were extracted from the database of the RDPLF. The covariates extracted from the registry were gender, comorbidities, diabetes mellitus, underlying nephropathy, PD modality at dialysis initiation (CAPD or APD) and starting PD after haemodialysis (HD) or transplantation failure. To assess patient comorbidities, we extracted the Charlson comorbidity index (CCI) from the database and calculated the modified CCI by subtracting the age subscore. Suboptimal PD initiation was defined as time spent on HD before PD of < 1 month [13].

Centre characteristics (Level 2 covariates)

To obtain data about centre characteristics, an additional questionnaire was sent to each PD facility. Subsequently, information about the centres was collected by interviewing the head nurse of each PD centre regarding centre characteristics during the study period. The covariates used to describe centre organization were as follows: full-time nurse (nurses dedicated only to PD), part-time nurse (nurses specialized in PD and also involved in other activities), nephrologists specialized in PD and home visits by PD nurses. The number of nephrologists and nurses per PD centre was also noted. Centre experience was characterized by the number of incident PD patients per centre and per year. Centres were separated by category: academic, community, non-profit and private. Centre environment was estimated by the district characteristics and involved the percentage of ESRD patients unable to walk alone, the percentage of patients with family caregivers, the median age at dialysis initiation and the private nurse density per 1000 habitants. Data about the centres' districts were extracted from the French Epidemiological Network and Information in Nephrology. Data on private nurse density in the districts were obtained from the National Institute for Statistics and Economic Studies.

Statistical analysis

Categorical covariates were expressed as frequencies and percentages and continuous covariates were expressed as the median (first and third quartiles).

The dependent covariate was nurse-assisted PD. To provide additional information regarding the factors associated with the modality of assisted PD, a multinomial regression model was conducted for the bivariate analysis with self-PD as the reference class. This allowed us to estimate the statistical significance of the difference between two associations and thus to estimate which assistance modality the covariate was more associated with (e.g. nurse-assisted PD or family-assisted PD, with self-PD as a reference).

The family-assisted patients were subsequently excluded from the original data set and hierarchical modelling was used to assess which patient and centre characteristics were associated with nurse-assisted PD. The centre effect on the utilization of nurse-assisted PD at dialysis initiation was estimated by the variance of the random effect. Patient characteristics were selected for the multilevel multivariate analysis if the P was < 0.20 in the logistic regression model. Because one of the objectives of the study was to estimate the centre effect, centre covariates were entered in the multilevel multivariate analysis *a priori*. An empty model (Model 0), with centre as a random effect, was compared with a logistic empty model to detect the centre effect, then logistic regression modelling was performed with the centre as a random effect and patient characteristics (Level 1). Subsequently, centre organization and centre characteristics (Level 2) were included as fixed effects [14]. To quantify the heterogeneity between centres regarding the utilization of assisted PD, the intraclass correlation coefficient (ICC) was calculated. Thereafter, individual covariates were included in the model to investigate whether centre heterogeneity was explained by the patient composition of the centre. Centre covariates were then included to investigate whether the centre effect was influenced by centre characteristics and organization. To estimate the contribution of the covariates introduced in each model, the proportional change in variance was calculated. To express the uncertainty of the estimator, the 95% confidence interval (CI) was utilized in the multivariate analysis. Statistical analyses were performed with R 3.1.2 (R Foundation for Statistical Computing, Vienna, Austria), including the lme4 and nnet packages.

The RDPLF was approved by the French National Ethics Committee (Commission Nationale de l'Informatique et des Libertés). This study took place within the framework of this authorization.

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Table 1. Patient characteristics ($N = 2269$)

Covariate	Family-assisted ($n = 114$)	Self-care ($n = 1883$)	Nurse-assisted ($n = 272$)
Age at PD initiation, median (IQR), years	58 (51–62)	49 (38–57)	58 (51–62)
CCI, median (IQR)	6 (4–7)	3 (2–4)	6 (4–7)
Modified CCI, median (IQR)	5 (3–6)	2 (2–3)	4 (3–6)
Modified CCI by categories, *n* (%)			
2	14 (12)	672 (36)	28 (10)
3	6 (5)	462 (25)	28 (10)
4	13 (11)	311 (17)	25 (9)
5	14 (12)	180 (10)	43 (16)
6	20 (18)	117 (6)	55 (20)
≥7	47 (41)	141 (7)	94 (34)
Gender (male), *n* (%)	73 (64)	1144 (61)	133 (49)
Diabetes, *n* (%)	59 (52)	297 (16)	124 (46)
Underlying nephropathy, *n* (%)			
Unknown	12 (11)	166 (9)	24 (9)
Interstitial nephritis	7 (6)	122 (6)	25 (0)
Glomerulonephritis	11 (10)	564 (30)	26 (10)
Diabetic	43 (38)	205 (11)	77 (28)
Polycystic kidney disease	4 (4)	250 (13)	6 (2)
Miscellaneous	6 (5)	125 (7)	12 (4)
Uropathy	6 (5)	113 (6)	10 (4)
Vascular	22 (19)	243 (13)	80 (29)
Systemic disease	3 (3)	95 (5)	12 (4)
First PD modality (CAPD)	60 (53)	1189 (63)	208 (76)
Treatment before PD, *n* (%)			
Haemodialysis	21 (18)	354 (19)	65 (24)
Not on dialysis	88 (77)	1400 (74)	196 (72)
Renal transplantation	5 (4)	129 (7)	11 (4)
Suboptimal starter, *n* (%)	10 (9)	10 (9)	257 (11)

Missing data

The rate of missing data was <15% for each covariate of the data set; multiple imputation by chained equation was performed for all missing data.

RESULTS

Patient characteristics

Patient characteristics are presented in Table 1. There were 2269 patients 18–65 years of age treated in 127 centres from 77 districts in the final data set. Of these patients, 114 (5%) were using family-assisted PD and 272 (12%) were on nurse-assisted PD. The median age was 51 years (interquartile range [IQR] 40–59), the median CCI was 3 (IQR 2–5) and the sex ratio (male:female) was 1350:919. There were 480 diabetic patients (21%). Assisted PD patients were older, more comorbid and more frequently diabetic than their counterparts. Nurse-assisted PD patients were more frequently treated with CAPD than family-assisted patients and self-care PD patients.

Centre characteristics

Centre characteristics are presented in Table 2. Among the 127 centres, there were 72 (56%) community hospital centres, 20 (16%) non-profit centres, 20 (16%) private centres and 15 (12%) academic centres. Of these 127 centres, 96 (76%) treated < 10 new PD patients per year. Nurse home visits were performed by 111 (87%) centres. Among those 111 centres, 86 (68%) provided home visits before starting PD, 106 (84%) at PD initiation, 14 (11%) at 3 months after PD initiation and 21 (17%) at 6 months after PD initiation. There were part-time nurses in 86 centres (68%) and full-time nurses in 31 centres (24%). There were 77 districts that corresponded to the 127 centres.

Bivariate analysis for the two types of assistance

Results are presented in Tables 3 and 4. In the multinomial regression analysis, patient age expressed by decade [odds ratio (OR) 1.72 (95% CI 1.46–2.02)] was associated with the likelihood of being treated with nurse-assisted PD and being treated by family-assisted PD. The difference of the association was statistically significant, as the link between age and nurse-assisted PD was stronger than the link between age and family-assisted PD. Gender [OR 0.48 (95% CI 0.36–0.64), female as reference class] was only associated with nurse-assisted PD. Comorbidity and underlying nephropathy were associated with both nurse-assisted PD and family-assisted PD, but there was no statistical difference between the two association. Patients treated in a centre with >10 new patients per year were more likely to be assisted by a nurse. There was no association between centre experience and family-assisted PD. Patients treated in centres with full-time nurses dedicated to PD were less likely to be treated with nurse-assisted PD. In contrast, there was no statistical association between centre organization

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RESULTS

Patient characteristics

Patient characteristics are presented in Table 1. There were 2269 patients 18–65 years of age treated in 127 centres from 77 districts in the final data set. Of these patients, 114 (5%) were using family-assisted PD and 272 (12%) were on nurse-assisted PD. The median age was 51 years (interquartile range [IQR] 40–59), the median CCI was 3 (IQR 2–5) and the sex ratio (male:female) was 1350:919. There were 480 diabetic patients (21%). Assisted PD patients were older, more comorbid and more frequently diabetic than their counterparts. Nurse-assisted PD patients were more frequently treated with CAPD than family-assisted patients and self-care PD patients.

Centre characteristics

Centre characteristics are presented in Table 2. Among the 127 centres, there were 72 (56%) community hospital centres, 20 (16%) non-profit centres, 20 (16%) private centres and 15 (12%) academic centres. Of these 127 centres, 96 (76%) treated < 10 new PD patients per year. Nurse home visits were performed by 111 (87%) centres. Among those 111 centres, 86 (68%) provided home visits before starting PD, 106 (84%) at PD initiation, 14 (11%) at 3 months after PD initiation and 21 (17%) at 6 months after PD initiation. There were part-time nurses in 86 centres (68%) and full-time nurses in 31 centres (24%). There were 77 districts that corresponded to the 127 centres.

Bivariate analysis for the two types of assistance

Results are presented in Tables 3 and 4. In the multinomial regression analysis, patient age expressed by decade [odds ratio (OR) 1.72 (95% CI 1.46–2.02)] was associated with the likelihood of being treated with nurse-assisted PD and being treated by family-assisted PD. The difference of the association was statistically significant, as the link between age and nurse-assisted PD was stronger than the link between age and family-assisted PD. Gender [OR 0.48 (95% CI 0.36–0.64), female as reference class] was only associated with nurse-assisted PD. Comorbidity and underlying nephropathy were associated with both nurse-assisted PD and family-assisted PD, but there was no statistical difference between the two association. Patients treated in a centre with >10 new patients per year were more likely to be assisted by a nurse. There was no association between centre experience and family-assisted PD. Patients treated in centres with full-time nurses dedicated to PD were less likely to be treated with nurse-assisted PD. In contrast, there was no statistical association between centre organization

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Table 2. Centre characteristics ($N = 127$)

Covariate	*n*	%
Centre experience (new patients per year)		
≤10	96	76
Type of centre		
Non-profit	20	16
Community hospital	72	56
Academic hospital	15	12
Private hospital	20	16
Homes visits		
Home visit	111	87
Before starting PD	86	68
At PD initiation	106	84
3 months after PD initiation	14	11
6 months after PD initiation	21	17
Annually	30	23
Centre organization		
Full-time nurses	31	24
Part-time nurses	86	68
Other	10	8
Nephrologists specialized in PD	82	65
Centre environment (district characteristics), median (IQR)		
Inability to walk (% of ESRD patients within the district)	4.8 (3.5–7.5)	
Family caregiver (% of ESRD patients within the district)	11.9 (7.10–15.30)	
Median age at dialysis initiation (in the district)	71 (69–73)	
Private nurse density (per 1000 habitants in the district)	129 (104–167)	

Table 3. Association between patient characteristics and assistance modality (multinomial model, reference level:self-care PD) ($N = 2269$)

Covariate	Family-assisted versus self-care PD, OR (95% CI)	Nurse-assisted versus self-care PD, OR (95% CI)
Age at PD initiation (decade)	1.25 (1.01–1.56)	1.72 (1.46–2.02)**
Gender (male)	0.94 (0.62–1.43)	0.48 (0.36–0.64)*
Diabetes	1.33 (0.66–2.66)	1.44 (0.89–2.32)
Modified CCI (by categories)		
2	Ref	Ref
3	0.89 (0.38–2.05)	1.21 (0.75–1.95)
4	3.22 (1.62–6.40)	2.45 (1.53–3.94)
5	4.43 (2.14–9.15)	4.47 (2.74–7.28)
6	6.16 (2.70–14.05)	4.26 (2.31–7.86)
≥7	8.88 (4.17–18.91)	5.82 (3.34–10.15)
Underlying nephropathy		
Polycystic kidney disease	Ref	Ref
Unknown	3.60 (1.11–11.72)	5.59 (2.17–14.38)
Interstitial nephritis	3.73 (1.05–13.23)	9.84 (3.84–25.20)
Glomerulonephritis	1.13 (0.35–3.66)	2.20 (0.87–5.52)
Diabetes	2.92 (0.87–9.82)	4.01 (1.54–10.43)
Miscellaneous	2.28 (0.60–8.61)	4.11 (1.44–11.72)
Urologic	4.52 (1.19–17.06)	6.20 (2.10–18.28)
Vascular	3.15 (1.03–9.62)	8.28 (3.46–19.84)
Systemic disease	1.73 (0.36–8.33)	5.00 (1.74–14.38)
Suboptimal starter	1.11 (0.55–2.24)	1.18 (0.72–1.93)
Treatment before PD		
Not on dialysis	Ref	Ref
Haemodialysis	0.88 (0.52–1.48)	1.30 (0.92–1.84)
Transplantation	0.83 (0.31–2.21)	0.75 (0.37–1.50)

P-values are provided only for the statistical difference between nurse-assisted PD and family-assisted PD when the covariate is associated with the two modalities of assistance.
*$P < 0.01$.
**$P < 0.001$.

and family-assisted PD. There was no meaningful relationship between centre category, centres with nephrologists specialized in PD and the utilization of nurse-assisted PD or family-assisted PD.

Multilevel analysis for nurse-assisted PD

The variance of the random effect was 0.45. That means that there was a significant variation across PD centres regarding the utilization of nurse-assisted PD (Table 5). The ICC was 0.12, indicating that 12% of the variance of the utilization of nurse-assisted PD was attributable to differences between centres. At the individual level, age expressed by decade [OR 1.79 (95% CI 1.51–2.13)], gender [OR 0.47 (95% CI 0.35–0.64), female as reference class], modified CCI, underlying nephropathy and treatment by HD before PD initiation [OR 1.48 (95% CI 1.02–2.15)] were associated with nurse-assisted PD utilization. The variance of the random effect increased by 19% after adjusting for patient characteristics, meaning that the centre effect was not due to differences in patient characteristics between centres. The variance of the random effect and the ICC decreased (0.37 and 0.10, respectively) when centre characteristics were entered in the model. However, no centre covariate was significantly associated with the utilization of nurse-assisted PD. Thus the variation between centres was not fully explained by the centre characteristics collected in our study, including centre organization, centre experience and centre environment.

DISCUSSION

Home care assistance is also used to treat non-elderly patients on PD in France, as 12% of incident PD patients 18–65 years of age were treated with nurse-assisted PD in our study. In view of these results, one may hypothesize that patient incapability to perform PD at the start of dialysis is also a common situation in the non-elderly population.

As expected, comorbid conditions were linked to the utilization of assisted PD. This finding is consistent with the fact that comorbidities are associated with disabilities such as neuropathy, visual impairment and muscle wasting that could decrease the patient's ability to perform PD exchanges. It has been demonstrated that among older subjects on assisted PD, functional impairment is highly prevalent and associated with comorbidities [15]. In our study, the patient's age was independently associated with nurse-assisted PD. Patients included in our study were < 65 years of age, which consequently raises the hypothesis of an earlier functional decline in ESRD patients. Female gender was associated with nurse assistance in the multivariate analysis. Differences in lifespan between genders in the general population that could lead to a greater percentage of social isolation of women on dialysis may explain this observation [16].

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Table 5. Continued

Fixed effects	Empty model	Model 1, OR (95% CI)	Model 2, OR (95% CI)
Treatment before PD			
Not on dialysis		Ref	Ref
Haemodialysis		1.49 (1.03–2.15)	1.48 (1.02–2.15)
Transplantation		0.75 (0.36–1.53)	0.75 (0.37–1.55)
Level 2: centres			
Centre experience (new patients per year)			
≤10	–	–	Ref
>10			0.97 (0.61–1.55)
Type of centre			
Non-profit	–	–	Ref
Community hospital			0.91 (0.49–1.69)
Academic hospital			0.77 (0.40–1.49)
Private hospital			0.51 (0.20–1.26)
Centre organization			
Other	–	–	Ref
Full-time nurses			0.52 (0.25–1.09)
Part-time nurses			0.70 (0.35–1.40)
Inability to walk (% of ESRD patients within the district)	–	–	1.00 (0.94–1.07)
Family caregiver (% of ESRD patients within the district)			1.01 (0.98–1.05)
Private nurse density (per 1000 habitants)			
≤150	–	–	Ref
>150			0.89 (0.58–1.39)
Random effects			
Level 2 variance (SD)	0.451 (0.672)	0.449 (0.670)	0.373 (0.611)
LRT P-value	<0.001	–	–
ANOVA P	–	<0.001	<0.001
ICC	0.12	0.12	0.10
PCV	–	−0.19	0.17

ANOVA: analysis of variance; ICC: Intraclass Coefficient Correlation; LRT: Likelihood Ratio Test; PCV: Proportional change in variance; SD: Standard Deviation.
**P < 0.001.

able to follow the education programme recommended by the ISPD. However, because of the period of our study, these recommendations could not have influenced the nurse assessments of the patients' capability to become autonomous. To our knowledge there is no validated tool that could help nurses select which patients need assistance. In our study, there was significant variability between centres regarding the utilization of nurse-assisted PD; 12% of the variance of the utilization of nurse-assisted PD was linked to the centre effect. However, centre experience and organization did not influence either the rate of the utilization of assisted PD or the assistance modality. In view of the heterogeneity between centres, one cannot exclude that in some cases the decision about nurse assistance was not appropriate. Even if nurse-assisted PD is less expensive than in-centre HD, there is an additional cost due to patient assistance in a situation where the allocation of resources must be prioritized [21]. Furthermore, lack of assistance in a situation where assistance is necessary can also affect the outcome on PD. Nevertheless, the absence of a standardized process does not necessarily signify that patient selection for assisted PD is not adequate. However, we believe that the construction and validation of a tool for relevant selection of patients is clearly needed. Patients' opinions and expectations may also influence the choice for assisted PD.

The main limitation of our study is the evolution of assistance over time, which reflects the ability to become autonomous after a certain time of assistance, but which was not explored in our report.

In conclusion, in France, even among non-elderly patients, nurse-assisted PD is necessary. Assisted PD is associated with patient characteristics. The heterogeneity between centres regarding the utilization of nurse assistance indicates that studies are needed to identify which patients must be assisted.

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CONFLICT OF INTEREST STATEMENT

None declared.

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8. Evaluation du patient pour l'attribution d'assistance

8.1. Objectif

L'objectif principal de notre étude était d'explorer, à l'échelon national, le lien entre l'évaluation subjective par l'infirmière de dialyse péritonéale de l'incapacité du patient à être autonome et l'utilisation d'une assistance par une infirmière à domicile ou par la famille pour le traitement par dialyse. L'objectif était également de déterminer si une dysfonction cognitive, une impotence fonctionnelle, ou un déficit auditif et/ou visuel estimé par l'infirmière étaient associés à l'utilisation de la DP assistée quelle que soit sa modalité.

8.2. Principaux résultats

Caractéristiques de la population

4101 patients ont débuté un traitement par la DP au cours de la période de l'étude. Sur ces 4101 patients, 2098 étaient traités par DP assistée, 403 par DP assistée par la famille et 1695 par DP assistée par une infirmière. Les patients en DP assistée par la famille et en DP assistée par une infirmière étaient plus âgés que les patients autonomes. Les patients en DP assistée par une infirmière étaient moins fréquemment des hommes que ceux en DP assistée par la famille et des patients autonomes (55%, 63% et 64%, respectivement). Les patients traités par DP assistée présentaient plus de comorbidités que les patients autonomes (ICC médian : 4 pour le groupe DP assistée par la famille ou un infirmier par rapport à 3 pour le groupe autonome). Les patients en DP assistée par la famille et les patients en DP assistée par une infirmière étaient plus fréquemment atteints de diabète que les patients autonomes (45%, 43% et 20%, respectivement). Les patients en DP étaient plus fréquemment traités par DPCA que les patients autonomes.

Évaluation infirmière

Le taux d'incapacité des patients à être autonome après l'évaluation subjective par l'infirmière était de 320 sur 403 (79%) dans le groupe en DP assistée par la famille, 132 sur 2003 (7%) dans le groupe autonome et 1487 sur 1696 (88%) dans le groupe DP assisté par une infirmière. Une déficience fonctionnelle était enregistrée chez 96 /03 (24%) des patients en DP assistée par la famille, 91/2003 (5%) des patients autonomes et 239/1696 (14%) des patients assistés par une IDE. Des dysfonctions cognitives étaient observées chez 58 patients sur 14 (14%) du groupe assisté par la famille, 139 patients sur 7 (7%) dans le groupe autonome, et 282 sur 1696 (17%) du groupe assisté par une infirmière. Il y avait 149 patients sur 403 (37%), 311 sur 16 (16%) et 596 sur 1696 (35%) atteints de surdité et/ou de déficience visuelle en DP assistée par la famille, pour les patients autonomes et en DP assistée par une IDE respectivement.

Résultats

L'évaluation subjective par l'infirmière de l'incapacité du patient à être autonome était associée à l'utilisation de la DP assistée par la famille ou par une infirmière.

La probabilité d'être traité par DP assistée par la famille ou par une infirmière était plus élevé chez les patients présentant une impotence fonctionnelle. La probabilité d'être en DP assistée par la famille ou en DP assistée par une infirmière était plus importante lorsque le patient présentait une dysfonction cognitive. La surdité et/ou une déficience visuelle étaient associées à la DP assistée quelle que soit sa modalité. Il n'existait pas d'interaction entre le dysfonctionnement cognitif, la déficience fonctionnelle et la surdité et/ou la déficience visuelle.

8.3. Utilité des résultats

Notre étude montre que l'utilisation de la DP assistée était fortement liée à l'évaluation faite par l'infirmière de DP de la capacité du patient à être traité par la dialyse autonome.

Dans une étude réalisée au Canada sur l'utilisation de la dialyse péritonéale assistée, un questionnaire protocolisé évaluant la force, la dextérité, la vision et les déficits cognitifs du patient était utilisé pour sélectionner les patients nécessitant une assistance [62]. Cependant ce travail ne donnait pas d'information concernant l'association entre l'évaluation du patient et l'utilisation de la DP assistée. Une échelle permettant d'estimer la capacité du patient à être autonome en DP a été validée en Chine [111]. Cependant, le lien entre l'échelle d'évaluation, construite dans le contexte chinois, et l'utilisation de la DP assistée par une infirmière ou de la famille n'a pas été évalué. Le questionnaire LC-GAD (Validation des soins dispensés aux adultes en dialyse), validé au Canada, mesure la quantité d'activités menées par les aidants naturels indépendamment de leur impact émotionnel [112]. Il n'y a pas d'étude concernant l'influence de la charge de travail des soignants et l'utilisation de la DP assistée par une infirmière.

Il est possible que l'évaluation subjective de la capacité d'autonomie réalisée par l'infirmière était influencée par le fardeau de la maladie pour les aidants familiaux [62,75]. Il a été montré que l'évaluation subjective de l'état de santé d'un patient est un bon indicateur du devenir du patient, ainsi la « surprise question » était un facteur prédictif de la mortalité à 12 mois des patients en DP [113].

Les données de PDOPPS montrent que la prévalence de l'incapacité fonctionnelle est importante chez les patients traités par la dialyse péritonéale [114]. Parmi 74 patients âgés de plus de 65 ans traités par dialyse péritonéale, 8 seulement étaient totalement indépendants pour les activités de la vie quotidienne et les activités instrumentales de la vie quotidienne [107]. On peut émettre l'hypothèse que le déficit fonctionnel était associé à une diminution de la dextérité donc à une moins bonne capacité à manipuler les dispositifs de DP.

Dans notre étude, l'incapacité fonctionnelle estimée par l'infirmière était associée à l'utilisation de l'assistance par la famille ou par une infirmière. Néanmoins, dans le RDPLF, aucune information n'est collectée sur les outils utilisés par les infirmières pour évaluer la capacité fonctionnelle du patient, il est possible que l'évaluation varie d'un centre à l'autre.

La prévalence des troubles cognitifs est plus élevée chez les patients insuffisants rénaux au stade terminal que dans la population générale [115]. En outre, l'insuffisance rénale chronique est associée au déclin de la fonction cognitive [116,117]. Il a été démontré que la déficience cognitive mesurée avec l'évaluation cognitive de Montréal (MoCA) était associée à un risque plus élevé de péritonite chez les patients autonomes en DP [118]. Le dysfonctionnement cognitif était également associé à des infections de l'émergence du cathéter de dialyse péritonéale dans une étude récente [119]. La DP assistée pourrait être un facteur protecteur vis-à-vis de la péritonite chez les patients ayant un dysfonctionnement cognitif.

L'ISPD a émis des recommandations concernant l'enseignement de la DP. Le comité de liaison des soins infirmiers de l'ISPD propose d'utiliser plusieurs outils d'éducation en fonction du style d'apprentissage préféré du patient [103]. Dans une étude australienne il existait de grandes différences entre les centres dans les pratiques éducatives [21]. Des outils adaptés pourraient être utilisés pour former les patients à la DP souffrant de surdité et/ou de déficience visuelle. Ainsi, l'association entre surdité et/ou déficience visuelle et l'assistance pourrait refléter la difficulté de l'infirmière à éduquer le patient à la dialyse autonome.

Des études supplémentaires sont nécessaires pour identifier les outils utilisés par les infirmières pour mesurer l'incapacité du patient à être autonome. La performance des outils d'évaluation devra être évaluée.

8.4. Publication et communication

Notre travail a fait l'objet d'une publication dans le journal American Journal of Nephrology.

Il a également fait l'objet d'un poster au **14th European Peritoneal Dialysis Meeting** à Ljubljana en mai 2019 : "**How nurses select patients for assisted Peritoneal Dialysis - A cohort study with the data of the RDPLF**".

8.5. Article

Novel Research Findings

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Assessment for Assisted Peritoneal Dialysis by Peritoneal Dialysis Nurses: Results of a Cohort Study

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Keywords
Peritoneal dialysis · Assisted peritoneal dialysis · Nurses assessment

Abstract
Background: Selection of patients for assisted peritoneal dialysis (PD) is based on the nurse's assessment of the patient. There is no data available about the nurse's assessment of the PD patient at the initiation of PD to estimate the need for assisted PD at the national level. This study was carried out to evaluate the association between the nurse's subjective assessment of the patient's inability to be treated by self-care PD, the nurse evaluation of the patient disabilities and the utilization of nurse or family assisted PD. ***Methods:*** This was a retrospective study of patients starting PD between July 1, 2010 and 2015 and registered in the nurse section of the French Language PD Registry (RDPLF). Poisson regression and a linear regression model with a robust variance estimator were used for the statistical analysis to determine relative risks (RRs) and risk differences (RDs). ***Results:*** Of 4,101 PD patients, 403 were treated by family assisted PD, and 1,695 were treated by nurse-assisted PD. In the multivariate analysis, the nurse's subjective assessment of the patient's inability to be treated by self-care PD was associated with nurse-assisted PD (5.40 [4.58–6.35], 67% [64–70%]) and family assisted PD (11.11 [8.49–14.56], RD 62% [57–67%]). Nurse-assisted PD and family assisted PD were associated with functional impairment (RR 1.25 [95% CI 1.16–1.36], RD 14% [95% CI 10–19%] and RR 2.02 [95% CI 1.69–2.41], RD 27% [95% CI 20–34%] respectively), cognitive dysfunction (RR 1.23 [95% CI 1.15–1.32], RD 15% [95% CI 11–18%] and RR 1.73 [95% CI 1.39–2.16], RD 12% [95% CI 7–18%] respectively) and deafness (RR 1.10 [95% CI 1.04–1.16], RD 8% [95% CI 5–11%] and RR 1.46 [95% CI 1.22–1.74], RD 10% [95% CI 6–14%] respectively). ***Conclusion:*** Our results showed that the nurse's subjective assessment of the patient's inability to be treated by self-care PD and the patient's disabilities were strongly associated with the utilization of nurse- and family assisted PD.

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Introduction

Assisted peritoneal dialysis (PD) programs have been developed in many countries to allow patients who are not capable of manipulating PD devices to be treated by PD [1–9]. There are different modalities of assisted PD; patients can be assisted by a family member, a partner, a

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technician or a nurse and can be treated by assisted PD or by assisted continuous ambulatory peritoneal dialysis (CAPD). In France, nurse-assisted PD is fully covered by the French health insurance whatever the modality (APD or CAPD) at home or in a nursing home [4]. The patient chooses his home private nurses; these private nurses are then trained in the dialysis center by the PD nurses.

Technique survival and peritonitis risk were found to be similar between assisted PD and assisted CAPD [10, 11]. Compared with self-care PD and family assisted PD, nurse-assisted PD was associated with longer use of the technique [8]. Diabetic patients and elderly patients treated by nurse-assisted PD had a lower risk of peritonitis than those on family assisted or self-care PD [12, 13]. It has been demonstrated that, among the caregivers of patients receiving PD, there was a reduction in both quality of life and personal hygiene over time that may affect the outcome of assisted PD patients [14]. In every program, when PD is not performed by an unpaid caregiver (usually a family member), there is an additional cost for the assistance that is covered by the health care insurance provider [15].

Consequently, it is important to identify those patients who must be treated by assisted PD and which type of assistance (nurse or family assistance) must be provided. The decision to treat someone by assisted PD and the choice of the assistance modality (nurse vs. family) is based on a nurse's subjective assessment of the patient's ability to be on self-care PD and on the nurse's evaluation of the patient's ability to handle the PD devices patient's choice. Then it must be confirmed by a prescription from the nephrologist responsible of the patient. Therefore, if the PD team considers that the patient can perform self-care PD, he is trained for PD. However in France, he can choose to be assisted by a relative if he wants. If the nurses' assessment is that the patient cannot have self-PD, the patient can choose to be under family or nurse-assistance. The choice of the family caregiver is made by the patient. Neither the patient nor the caregiver is assessed with tools that have been validated in the field of PD for the evaluation of his ability to perform PD. To our knowledge there is no study available about tools that can be used to assess dexterity in PD patients.

Only one study from Canada has provided information about the criteria and tools that could be used to make the decision to assist a PD patient [16]. An Australian nurse team developed a tool, the Jo-Pre-training Assessment Tool (JPAT) to screen suitable candidates for the home dialysis program [17]. This is obviously relevant, as identifying patients with the greatest chance of learning is a matter of concern.

Although guidelines have been established for patient education pertaining to PD, there is no recommendation regarding the criterion that should be used to identify those patients who must be treated by assisted PD [18]. In one recent study, nurse-assisted PD utilization in non-elderly patients was associated with the center's practices, independent of the patient's characteristics [19]. To our knowledge, there is no data available about the nurse's assessment of the PD patient at the initiation of PD to estimate the need for assisted PD.

Our hypothesis is that a nurse's subjective assessment of the patient's inability to be treated by self-care PD, evaluated before PD start, is a good predictor of the use of assisted-PD and that this assessment can be easily resumed with the question "do you believe that the patient can be treated by self-care PD?"

The aim of this study was to explore, at the national level, the association between the nurse's subjective assessment of the patient's inability to be treated by self-care PD and the modality of assistance. The objective was also to estimate which factors of the nurse's evaluation of the patient's disabilities were associated with family-assisted or nurse-assisted PD.

Material and Methods

Study Population

This was a retrospective study based on the data of the nurse section of the French Language PD Registry (RDPLF). Of the 5,707 subjects older than 18 years old starting PD during the study period (July 1, 2010 until 2015), 4,101 patients were recorded in the nurse section of the RDPLF. Among the 154 participating centers of the RDPLF, 125 collect data for the nurse section of the registry. The nurse in charge of the patient records individual data before PD initiation and at the end of the education process. The nurse section of the RDPLF contains information about the patient's ability to be treated by self-care PD and about the patient's disabilities at dialysis initiation. Data from the core section of the registry database were also extracted and merged with the nurse section file.

Events of Interest

The events of interest were nurse-assisted PD and family-assisted PD recorded at the last follow-up date for each patient. In the case of PD cessation (death, transfer to HD, renal transplantation, loss of follow-up), the last observation of the assistance status was used (last observation carried forward).

Variables of Interest

The main objective of the study was to evaluate the role of the nurse's assessment before the initiation of PD, on the modality of assisted PD (nurse or family-assisted PD) used. In France, the nurse's assessment must be confirmed by a prescription from the patient's nephrologist that is used by private nurses in charge of patient assistance at home to submit a claim for payment from the

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healthcare insurance provider [4]. Family assistance and self-care PD also need to be confirmed by the nephrologist in charge of the patient since financial compensation from the healthcare insurance provider is given to everyone treated by home dialysis (except for those treated by nurse-assisted PD). The nurse's subjective assessment of the patient's inability to be treated by self-care PD ("do you believe that the patient can be treated by self-care PD?") and the nurse's evaluation of the patient's disabilities (functional impairment, deafness and/or visual impairment, cognitive dysfunction) are declarative variables collected in the nurse section of the registry. Age at PD initiation, sex, Charlson comorbidity index (CCI), diabetes mellitus, underlying nephropathy, PD modality at dialysis initiation (CAPD or APD) and treatment received before starting PD were extracted from the core section of the RDPLF. To assess patient comorbidities, we calculated the modified CCI by subtracting the age subscore from the CCI. Suboptimal PD initiation was defined as time spent on HD before PD of <1 month [20]. The type of center (nonprofit, community hospital, academic hospital and private hospital) and the center experience, defined by the number of new patients treated per year, were obtained from the database.

Statistical Analysis

Categorical covariates were expressed as frequencies and percentages. Continuous variables were expressed as the median with the first and the third quartiles. For the statistical analysis, we compared the family-assisted PD group with the self-care PD group and the nurse-assisted PD group with the self-care PD group (self-care PD group as reference class); the nurse-assisted PD group with the family-assisted PD group (nurse-assisted PD group as reference class). Logistic regression overestimates the relative risk (RR) when the rate of the event of interest is >10%. A prevalence ratio modeling that calculates RR was performed with a Poisson regression model to evaluate the association between the nurse's assessment and the modality of assistance [21]. To provide additional information, a risk difference (RD) analysis was also conducted with a linear regression model [22]. For the prevalence ratio and RD analysis, the 95% CIs, which represented the uncertainty of the estimates, were calculated with the robust variance method ("sandwich"). Covariates were selected for the multivariate models when the p value was lower than 0.20 in the bivariate analysis. The interaction between cognitive dysfunction, functional impairment and deafness and/or visual impairment was tested.

Statistical analyses were performed with R 3.4.4 (R Foundation for Statistical Computing).

Missing Data

The rate of missing data was <5% for each covariate of the dataset, and the multiple imputation by chained equation was used for all missing data. Five datasets were imputed, and one was selected for the statistical analysis based on the graphical representation of the imputed value.

Results

Patient Characteristics

There were 4,101 patients who started PD during the study period. Of these 4,101 patients, 2,098 were treated by assisted PD, 403 were on family-assisted PD, and 1,695 were on nurse-assisted PD. Family-assisted PD and nurse-assisted PD patients were older than the self-care PD patients (median age 76, 80, and 57 years, respectively). Nurse-assisted PD patients were less frequently male than the family-assisted PD and the self-care PD patients (55, 63, and 64%, respectively). Patients treated by assisted PD had more comorbidities than self-care PD patients (median CCI 4 for the family- and nurse-assisted PD group versus 3 for the self-care PD group). Family-assisted PD patients and nurse-assisted PD patients were more frequently diabetic than self-care PD patients (45, 43, and 20%, respectively). Assisted-PD patients were more frequently treated by CAPD than self-care PD patients. The results of the univariate analysis are provided in Table 1.

Nurse Assessment

The rate of patient inability to be treated by self-care PD after the nurse's subjective assessment was 320 out of 403 (79%) in the family-assisted PD group, 132 out of 2,003 (7%) in the self-care PD group, and 1,487 out of 1,696 (88%) in the nurse-assisted PD group. A functional impairment was recorded in 96 out of 403 (24%), 91 out of 2,003 (5%), and 239 out of 1,696 (14%) individuals in the family-assisted PD, self-care PD, and nurse-assisted PD groups respectively. Cognitive dysfunction was noted in 58 out of 403 (14%) patients in the family-assisted group, 139 out of 2,003 (7%) patients in the self-care PD group, and 282 out of 1,696 (17%) patients in the nurse-assisted group. There were 149 out of 403 (37%), 311 out of 2,003 (16%), and 596 out of 1,696 (35%) patients who had deafness and/or visual impairment in the family-assisted, self-care PD, and nurse-assisted PD groups respectively.

Bivariate Analysis

In the bivariate analysis, there was an association between the nurse's subjective assessment of the patient's inability to be treated by self-care PD and the use of both family-assisted PD (RR 15.92 [95% CI 12.85–19.71], RD 66% [95% CI 62–71%]) and nurse-assisted PD (RR 9.17 [95% CI 8.05–10.45], RD 82% [95% CI 80–84%]). Patients with a functional impairment were more likely to be treated by family-assisted PD (RR 3.70 [95% CI 3.09–4.42], RD 37% [95% CI 30–45%]) and by nurse-assisted PD (RR 1.68 [95% CI 1.55–1.81], RD 29% [95% CI 24–34%]) than patients without a functional impairment. Cognitive dysfunction was also associated with family-assisted PD (RR 1.88 [95% CI

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Table 1. Characteristics of the study's population

Covariate	Number = 4,101		
	family-assisted (n = 403)	self-care (n = 2,003)	nurse-assisted (n = 1,695)
Age at PD initiation, years, median (IQR)	76 (66–82)	57 (44–68)	80 (72–84)
Modified CCI, median (IQR)	4 (3–6)	3 (2–4)	4 (3–6)
Modified CCI by categories, n (%)			
2	74 (18)	993 (50)	282 (17)
3	66 (16)	354 (18)	308 (18)
4	79 (20)	270 (13)	335 (20)
5	72 (18)	175 (9)	316 (19)
6	48 (12)	89 (4)	202 (12)
≥7	64 (16)	122 (6)	252 (15)
Gender, male, n (%)	255 (63)	1,286 (64)	937 (55)
Diabetes, n (%)	181 (45)	405 (20)	722 (43)
Underlying nephropathy, n (%)			
Unknown	54 (13)	229 (11)	208 (12)
Interstitial nephritis	27 (7)	146 (7)	98 (6)
Glomerulonephritis	35 (9)	474 (24)	88 (5)
Diabetic	99 (25)	241 (12)	430 (25)
Polycystic kidney disease	12 (3)	256 (13)	37 (2)
Uropathy	12 (3)	149 (7)	39 (2)
Vascular	148 (37)	416 (21)	742 (44)
Miscellaneous	16 (4)	92 (5)	53 (3)
PD modality (CAPD), n (%)	263 (65)	867 (43)	1,398 (82)
Treatment before PD, n (%)			
Hemodialysis	76 (19)	385 (19)	273 (16)
Not on dialysis	325 (79)	1,501 (75)	1,406 (83)
Renal transplantation	8 (2)	122 (6)	16 (1)
Suboptimal starter, n (%)	39 (10)	201 (10)	223 (13)
Center experience (new patients per year), n (%)			
≤10	193 (48)	980 (49)	711 (42)
11–20	158 (39)	697 (35)	728 (43)
>20	52 (13)	326 (16)	256 (15)
Type of center, n (%)			
Nonprofit	73 (18)	481 (24)	317 (19)
Community hospital	231 (57)	995 (50)	1,006 (59)
Academic hospital	49 (12)	329 (16)	211 (12)
Private hospital	50 (12)	198 (10)	161 (9)
Nurse's evaluation, n (%)			
Inability to be treated by self-care PD	320 (79)	132 (7)	1,487 (88)
Functional impairment	96 (24)	91 (5)	239 (14)
Cognitive dysfunction	58 (14)	139 (7)	282 (17)
Deafness and/or visual impairment	149 (37)	311 (16)	596 (35)

PD, peritoneal dialysis; IQR, interquartile range; CCI, Charlson comorbidities index; CAPD, continuous ambulatory PD.

1.49–2.39], RD 14% [95% CI 7–20%]) and with nurse-assisted PD (RR 1.56 [95% CI 1.44–1.68], RD 24% [95% CI 19–29%]). The risk of being treated by family-assisted PD (RR 2.47 [95% CI 2.06–2.96], RD 19% [15–24%]) or by nurse-assisted PD (RR 1.67 [95% CI 1.57–1.78], RD 26% [95% CI 23–30%]) was higher for patients with deafness and/or visual impairment. Age, sex, comorbidities, and diabetes were associated with nurse- and family-assisted PD. The results of the bivariate analysis are displayed in Table 2.

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Table 2. Bivariate analysis results: association between the study population's characteristics and modality of assistance (prevalence ratio [RR] and RD modeling)

Covariate	Family-assisted vs. self-care PD (ref.)		Nurse-assisted vs. self-care PD (ref.)	
	RR (95% CI)	RD (95% CI)	RR (95% CI)	RD (95% CI)
Age at PD initiation, years	1.08 (1.07 to 1.10)	1 (1 to 1)	1.12 (1.11 to 1.13)	2 (2 to 2)
Modified CCI (by categories)				
2	Ref.	Ref.	Ref.	Ref.
3	1.88 (1.52 to 2.33)	9 (5 to 12)	1.55 (1.45 to 1.65)	3 (–2 to 9)
4	2.49 (2.05 to 3.01)	16 (11 to 20)	1.74 (1.64 to 1.85)	2 (–4 to 7)
5	3.03 (2.54 to 3.64)	22 (16 to 28)	1.92 (1.81 to 2.03)	2 (–3 to 8)
6	3.37 (2.78 to 4.08)	28 (20 to 36)	1.94 (1.83 to 2.06)	1 (–5 to 8)
≥7	3.41 (2.86 to 4.06)	27 (20 to 34)	1.94 (1.83 to 2.05)	0 (–5 to 7)
Diabetes	2.55 (2.14 to 3.03)	19 (15 to 23)	1.69 (1.58 to 1.81)	26 (23 to 30)
Gender, male	0.97 (0.81 to 1.16)	–1 (–4 to 2)	0.82 (0.76 to 0.88)	–9 (–12 to –6)
Underlying nephropathy				
Polycystic kidney disease	Ref.	Ref.	Ref.	Ref.
Unknown	0.14 (0.07 to 0.25)	–25 (–30 to –19)	0.18 (0.13 to 0.25)	–51 (–57 to –46)
Interstitial nephritis	0.63 (0.46 to 0.87)	–10 (–17 to –3)	0.72 (0.63 to 0.81)	–16 (–22 to –10)
Glomerulonephritis	0.51 (0.33 to 0.77)	–13 (–21 to 6)	0.59 (0.49 to 0.71)	–24 (–31 to –17)
Diabetes	0.22 (0.15 to 0.33)	–22 (–27 to –17)	0.23 (0.18 to 2.28)	–48 (–53 to –44)
Urologic	0.23 (0.12 to 0.43)	–22 (–28 to –15)	0.29 (0.21 to 0.40)	–43 (–52 to 36)
Vascular	0.90 (0.71 to 1.13)	–3 (–9 to 3)	1.00 (0.91 to 1.09)	0 (–5 to 5)
Miscellaneous	0.48 (0.29 to 0.81)	–14 (–2 to –6)	0.53 (0.41 to 0.68)	–27 (–36 to –19)
PD modality (CAPD)	2.14 (1.77 to 2.59)	12 (9 to 15)	2.99 (2.68 to 3.34)	41 (38 to 44)
Treatment before PD				
Not on dialysis	Ref.	Ref.	Ref.	Ref.
Hemodialysis	0.93 (0.74 to 1.19)	–1 (–5 to 3)	0.85 (0.78 to 0.94)	–7 (–11 to –3)
Transplantation	0.31 (0.09 to 1.04)	–11 (–16 to 7)	0.23 (0.14 to 0.37)	–37 (–42 to –31)
Suboptimal starter	0.95 (0.71 to 1.28)	0 (–5 to 4)	1.17 (1.06 to 1.29)	8 (3 to 13)
Center experience				
≤10	Ref.	Ref.	Ref.	Ref.
11–20	1.12 (0.92 to 1.36)	2 (–1 to 5)	1.21 (1.13 to 1.31)	9 (5 to 12)
>20	0.83 (0.62 to 1.10)	–3 (–7 to 1)	1.04 (0.94 to 1.15)	19 (–27 to 7)
Type of center				
Nonprofit	Ref.	Ref.	Ref.	Ref.
Community hospital	1.42 (1.12 to 1.81)	6 (2 to 9)	1.26 (1.16 to 1.38)	10 (6 to 15)
Academic hospital	0.98 (0.71 to 1.35)	0 (–4 to 4)	0.99 (0.88 to 1.11)	–1 (–6 to 5)
Private hospital	1.48 (1.07 to 2.04)	7 (–12 to 13)	1.11 (0.98 to 1.26)	5 (–1 to 11)
Nurse's evaluation				
Functional impairment	3.70 (3.09 to 4.42)	37 (30 to 45)	1.68 (1.55 to 1.81)	29 (24 to 34)
Cognitive dysfunction	1.88 (1.49 to 2.39)	14 (7 to 20)	1.56 (1.44 to 1.68)	24 (19 to 29)
Deafness and/or visual impairment	2.47 (2.06 to 2.96)	19 (15 to 24)	1.67 (1.57 to 1.78)	26 (23 to 30)
Inability to be treated by self-care PD	15.92 (12.85 to 19.71)	66 (62 to 71)	9.17 (8.05 to 10.45)	82 (80 to 84)

PD, peritoneal dialysis; CCI, Charlson comorbidities index; CAPD, continuous ambulatory PD; RR, relative risk; RD, risk difference.

Multivariate Analysis

Nurse's Subjective Assessment

After adjustment for potential confounders, compared to self-care PD, the nurse's subjective assessment of the patients' inability to be treated by self-care PD was associated with use of family-assisted PD (RR 11.11 [95% CI 8.49–14.56], RD 62% [95% CI 57–67%]) and nurse-assisted PD (RR 5.40 [95% CI 4.58–6.35], RD 67 [95% CI 64–70%]). The results of the multivariate analysis are presented in Table 3.

Compared to nurse-assisted PD, after adjustment on age, sex, underlying nephropathy, PD modality, treatment before PD, suboptimal starters and center experience, family-assisted PD was not associated with the

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Table 3. Multivariable analysis results, association between the nurse's subjective assessment and the modality of assistance (prevalence ratio [RR] and RD modeling)

Covariate	Family-assisted vs. self-care PD (ref.)		Nurse-assisted vs. self-care PD (ref.)	
	RR (95% CI)	RD (95% CI)	RR (95% CI)	RD (95% CI)
Inability to be treated by self-care PD	11.11 (8.49 to 14.56)	62 (57 to 67)	5.40 (4.58 to 6.35)	67 (64 to 70)
Age at PD initiation	1.02 (1.01 to 1.02)	0 (0 to 0)	1.02 (1.01 to 1.02)	0 (0 to 0)
Modified CCI (by categories)				
2	Ref.	Ref.	Ref.	Ref.
3	1.34 (1.02 to 1.61)	1 (–1 to 4)	1.19 (1.10 to 1.29)	3 (0 to 5)
4	1.39 (1.01 to 1.02)	2 (–1 to 6)	1.19 (1.09 to 1.28)	2 (–1 to 5)
5	1.38 (1.09 to 1.77)	2 (–2 to 7)	1.29 (1.19 to 1.41)	7 (3 to 10
6	1.34 (1.03 to 1.75)	2 (–4 to 8)	1.22 (1.11 to 1.33)	4 (0 to 8)
≥7	1.48 (1.14 to 1.93)	5 (0 to 11)	1.31 (1.20 to 1.44)	6 (2 to 11)
Diabetes	1.14 (0.96 to 1.36)	4 (–1 to 8)	1.04 (0.98 to 1.10)	1 (–2 to 4)
Gender, male	–	–	0.91 (0.87 to 0.95)	–4 (–6 to –2)
Underlying nephropathy				
Polycystic kidney disease	Ref.	Ref.	Ref.	Ref.
Unknown	0.60 (0.36 to 1.00)	–1 (–7 to 4)	0.68 (0.54 to 0.86)	–6 (–11 to –2)
Interstitial nephritis	1.00 (0.79 to 1.27)	2 (–4 to 8)	1.03 (0.95 to 1.12)	1 (–3 to 5)
Glomerulonephritis	1.15 (0.83 to 1.60)	2 (–5 to 8)	1.06 (0.94 to 1.18)	0 (–6 to 4)
Diabetes	0.91 (0.68 to 1.22)	1 (–4 to 7)	0.79 (0.69 to 0.91)	2 (–6 to 1)
Urologic	0.97 (0.63 to 1.49)	3 (–3 to 9)	0.91 (0.76 to 1.08)	0 (–5 to 5)
Vascular	0.99 (0.82 to 1.19)	1 (–4 to 7)	1.03 (0.97 to 1.10)	2 (–2 to 5)
Miscellaneous	1.02 (0.68 to 1.52)	0 (–7 to 8)	1.06 (0.92 to 1.10)	0 (–7 to 6)
PD modality (CAPD)	0.95 (0.82 to 1.10)	–1 (–3 to 1)	1.13 (1.05 to 1.22)	3 (1 to 6)
Treatment before PD				
Not on dialysis	Ref.	Ref.	Ref.	Ref.
Hemodialysis	1.06 (0.91 to 1.24)	2 (–1 to 4)	1.05 (0.99 to 1.11)	2 (0 to 4)
Transplantation	1.11 (0.63 to 1.95)	1 (–2 to 4)	0.95 (0.67 to 1.35)	0 (–4 to –4)
Suboptimal starter	–	–	0.98 (0.92 to 1.04)	0 (–3 to 3)
Center experience				
≤10	Ref.	Ref.	Ref.	Ref.
11–20	1.34 (1.16 to 1.54)	5 (2 to 7)	1.07 (1.02 to 1.12)	4 (2 to 6)
>20	1.19 (0.89 to 1.59)	2 (–2 to 6)	1.16 (1.07 to 1.26)	6 (2 to 9)
Type of center				
Nonprofit	Ref.	Ref.	Ref.	Ref.
Community hospital	1.02 (0.78 to 1.34)	0 (–4 to 3)	1.11 (1.03 to 1.20)	3 (0 to 6)
Academic hospital	0.88 (0.65 to 1.19)	–2 (–6 to 1)	1.10 (1.01 to 1.20)	3 (0 to 6)
Private hospital	0.98 (0.72 to 1.32)	–1 (–6 to 3)	1.00 (0.91 to 1.11)	0 (–5 to 3)

PD, peritoneal dialysis; CCI, Charlson comorbidities index; CAPD, continuous ambulatory PD; RR, relative risk; RD, risk difference.

nurse's subjective assessment of the patients' inability to be treated by self-care PD (RR 1.07 [95% CI 0.99–1.15], RD 5% [95% CI –7 to 10]; data not shown).

Nurse's Assessment of the Patient's Disabilities

Compared to self-care PD, the likelihood of being treated by family-assisted PD (RR 2.02 [95% CI 1.69–2.41], RD 27% [95% CI 20–34%]) or by nurse-assisted PD (RR 1.25 [95% CI 1.16–1.36], RD 14% [95% CI 10–19%]) was higher for patients who had a functional impairment than for those who did not have a functional impairment. Patients with cognitive dysfunction had a greater chance of being treated by family-assisted PD (RR 1.73 [95% CI 1.39–2.16], RD 12% [95% CI 7–18%]) or nurse-assisted PD (RR 1.23 [95% CI 1.15–1.32] RD 15% [95% CI 11–18%]). Deafness and/or visual impairment were associated with family-assisted PD (RR 1.46 [95% CI 1.22–1.74], RD 10% [95% CI 6–14%]) and with nurse-assisted PD (RR 1.10 [95% CI 1.04–1.16], RD 8% [95% CI 5–11%]). There was no interaction between cognitive dysfunction, functional impairment and deafness and/or visual impairment. The results of the multivariate analysis are displayed in Table 4.

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Table 4. Multivariable analysis results, association between the nurse's assessment of the patient's disabilities and the modality of assistance (prevalence ratio [RR] and RD modeling)

Covariate	Model 1 family-assisted vs. self-care PD (ref.)		Model 2 nurse-assisted vs. self-care PD (ref.)	
	RR (95% CI)	RD (95% CI)	RR (95% CI)	RD (95% CI)
Functional impairment	2.02 (1.69 to 2.41)	27 (20 to 34)	1.25 (1.16 to 1.36)	14 (10 to 19)
Cognitive dysfunction	1.73 (1.39 to 2.16)	12 (7 to 18)	1.23 (1.15 to 1.32)	15 (11 to 18)
Deafness and/or visual impairment	1.46 (1.22 to 1.74)	10 (6 to 14)	1.10 (1.04 to 1.16)	8 (5 to 11)
Age at PD initiation, years	1.05 (1.04 to 1.06)	0 (0 to 1)	1.04 (1.04 to 1.04)	10 (11 to 13)
Modified CCI (by categories)				
2	Ref.	Ref.	Ref.	Ref.
3	1.28 (0.97 to 1.69)	0 (–3 to 4)	1.30 (1.18 to 1.43)	4 (1 to 8)
4	1.49 (1.13 to 1.98)	3 (–1 to 8)	1.31 (1.19 to 1.45)	5 (1 to 9)
5	1.64 (1.22 to 2.19)	5 (0 to 11)	1.45 (1.31 to 1.61)	9 (5 to 15)
6	1.78 (1.28 to 2.46)	8 (0 to 17)	1.45 (1.30 to 1.62)	12 (6 to 18)
≥7	1.81 (1.33 to 2.49)	9 (2 to 17)	1.55 (1.39 to 1.73)	13 (7 to 18)
Diabetes	1.26 (1.01 to 1.56)	5 (–1 to 11)	1.07 (1.00 to 1.16)	1 (–3 to 5)
Gender, male	–	–	0.79 (0.74 to 0.83)	–12 (–14 to –9)
Underlying nephropathy				
Polycystic kidney disease	Ref.	Ref.	Ref.	Ref.
Unknown	0.47 (0.26 to 0.84)	–5 (–13 to 2)	0.48 (0.37 to 0.64)	–20 (–26 to –14)
Interstitial nephritis	1.05 (0.77 to 1.43)	4 (–4 to 12)	0.95 (0.86 to 1.06)	2 (–8 to 3)
Glomerulonephritis	1.28 (0.87 to 1.88)	4 (–4 to 12)	1.05 (0.92 to 1.21)	–3 (–9 to 4)
Diabetes	0.73 (0.50 to 1.06)	0 (–7 to 7)	0.64 (0.54 to 0.77)	–10 (–15 to –4)
Urologic	0.91 (0.53 to 1.58)	2 (–5 to 10)	0.76 (0.61 to 0.96)	–5 (–12 to 1)
Vascular	1.07 (0.84 to 1.37)	4 (–3 to 11)	1.05 (0.97 to 1.13)	3 (–2 to 7)
Miscellaneous	1.05 (0.63 to 1.74)	0 (–9 to 10)	0.97 (0.80 to 1.18)	–6 (–15 to 2)
PD modality (CAPD)	1.08 (0.90 to 1.28)	2 (–1 to 5)	1.41 (1.28 to 1.54)	12 (9 to 15)
Treatment before PD				
Not on dialysis	Ref.	Ref.	Ref.	Ref.
Hemodialysis	1.19 (0.98 to 1.46)	3 (0 to 6)	1.08 (1.00 to 1.16)	3 (0 to 6)
Transplantation	0.91 (0.46 to 1.78)	–3 (–7 to 1)	0.73 (0.48 to 1.11)	–6 (–12 to –1)
Suboptimal starter	–	–	1.05 (0.97 to 1.14)	4 (0 to 7)
Center experience				
≤10	Ref.	Ref.	Ref.	Ref.
11–20	1.36 (1.10 to 1.56)	4 (1 to 7)	1.12 (1.06 to 1.19)	7 (4 to 10)
>20	1.28 (0.88 to 1.78)	2 (–2 to 7)	1.21 (1.09 to 1.35)	7 (3 to 11)
Type of center				
Nonprofit	Ref.	Ref.	Ref.	Ref.
Community hospital	1.17 (0.84 to 1.61)	1 (–3 to 5)	1.14 (1.03 to 1.27)	3 (–1 to 7)
Academic hospital	1.02 (0.70 to 1.46)	0 (–6 to 4)	1.14 (1.13 to 1.27)	3 (–1 to 8)
Private hospital	1.21 (0.84 to 1.75)	2 (–4 to 8)	1.01 (0.89 to 1.14)	–2 (–7 to 3)

PD, peritoneal dialysis; CCI, Charlson comorbidities index; CAPD, continuous ambulatory PD; RR, relative risk; RD, risk difference.

Compared to nurse-assisted PD, patients with functional impairment had a lower chance to be assisted by a family's member (RR 0.88 [95% CI 0.82–0.94], RD –10% [95% CI –15 to 5]). Cognitive dysfunction, deafness and/or visual impairment were not associated with the use of family-assisted PD (RR 1.04 [95% CI 0.99–1.10], RD 3% [95% CI 0–8]; RR 0.98 [95% CI 0.94–1.03], RD –1% [95% CI –5 to 2] respectively; data not shown).

Discussion/Conclusion

In our study, the nurse's assessment of the patient's inability to be treated by self-care PD was strongly associated with the utilization of assisted PD. These results emphasized the fact that the nephrologist's decision to use assisted PD was mainly based on the PD nurse's evaluation. In Portugal [9], China [5], Denmark [4], Canada

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[16] and the UK [3, 23], assisted PD program patients who were selected by the PD staff for assisted PD were characterized as frail, elderly patients who were unable to perform peritoneal exchanges. One study from Canada reported the use of a standardized questionnaire, completed by the PD unit staff, to capture the patient's strength, dexterity, vision and cognitive deficits [16]. However, no information was provided by the authors regarding the association between the patient's evaluation with the questionnaire and the utilization of assisted PD. The JPAT assess some relevant topics as physical stability, nutritional status, communication skills, ability to maintain self-care, social support, and psychological suitability [17]. However, there is no prospective study about the utilization of the JPAT in PD patients. A scale to estimate the effectiveness of the patient's self-management of PD has been validated in China [24]. To our knowledge, the association between the assessment scale and the utilization of nurse-assisted or family-assisted PD has not been evaluated. Furthermore, the assessment scale was constructed in the Chinese context. The Lay Care-Giving for Adults Receiving Dialysis questionnaire, validated in Canada, measured the quantity of caregiver activities independent of their emotional impact [25]. There is no study regarding the influence of the workload for the caregivers and the utilization of nurse-assisted PD.

In our study, the question "do you believe that the patient can be treated by self-care PD?," answered by the nurse in charge of the patient's education before the training initiation, was strongly associated with the utilization of assisted PD. The nurse's subjective assessment of the patient's inability to be treated by self-care PD was a global evaluation that estimated several dimensions associated with the patient's self-management capability. It can be speculated that the question also estimated the burden of the disease on the family caregivers that could influence the assessment of the inability to be treated by self-care PD [16–26]. The association between the nurse's subjective assessment and the utilization of assisted PD is consistent with the reliability of the nurse's evaluation of the patient outcome with the "surprise question" that has been shown to be a strong predictor of the 12-month mortality of patients on PD [27].

Data from the PDOPPS showed that functional dependence were highly prevalent in PD patients [28]. In a study from Canada, among 74 patients older than 65 years treated by PD, only 8 individuals were fully independent for activities of daily living and for instrumental activities of daily living [29]. It can be hypothesized that functional disability was associated with dexterity impairment and consequently with the ability to handle peritoneal devices. In our study, functional impairment estimated by PD nurses was associated with the utilization of nurse- and family-assisted PD. Nevertheless, in the RDPLF, there was no information collected about the tools used by nurses to evaluate the patient's functional capacity; consequently, the assessments may vary from one center to another.

Cognitive impairment prevalence is higher in end-stage renal disease patients compared with that in the general population [30]. Furthermore, chronic kidney disease is associated with cognitive function decline [31, 32]. It has been demonstrated that cognitive impairment measured with the Montreal Cognitive Assessment was associated with a greater risk of peritonitis in self-care PD patients [33]. Cognitive dysfunction was also associated with exit site infections in 1 study from the same team [34]. It has been suggested that assisted PD could protect patients with cognitive dysfunction from peritonitis. In our study, cognitive dysfunction evaluated by PD nurses was strongly associated with the utilization of family-assisted PD and nurse-assisted PD. Unfortunately, the results of tests used to evaluate cognitive dysfunction by PD nurses were not collected.

Surprisingly, deafness and/or visual impairment were associated with family- and nurse-assisted PD. The International Society for PD has recommended the standardization of teaching practices for PD for both nursing staff (trainers) and patients. The Nursing Liaison Committee of the International Society for PD proposed combining several education tools according to the patient's preferred learning style [18]. One study from Australia showed that there was wide variation between centers regarding educational practices [35]. There is no published evidence regarding patient training, and an educational curriculum will be tested in a randomized control study [35]. One may argue that adapted tools should be used to train PD patients with deafness and/or visual impairment to overcome barriers to self-care PD. Thus, the association between deafness and/or visual impairment may reflect the nurse's difficulty in coping with patient education in these situations.

The patient choice can be different from the nurse assessment, as a patient in France can ask for assistance even if he is able to perform by himself. In particular, in some families, the partner is trained to deliver family-as-

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sisted PD and help the patient even if he does not have disabilities.

Our study has some limitation. PD nurses experience and assertiveness may have influenced the decision to provide assistance. Data are not collected in the nursing core of the registry and to collect it retrospectively would have been biased (memory bias).

Our study showed that assisted PD utilization was strongly associated with the nurse's assessment of the patient's inability to be treated by self-care PD. Further studies are needed to identify which tools are used by PD nurses to measure the patient's inability to be treated by self-care PD and to investigate the accuracy of these tools to select patients for assisted PD.

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Statement of Ethics

The RDPLF was approved by the French National Ethics Committee (Commission Nationale de l'Informatique et des Libertés). This study took place within the framework of this authorization and includes ethical considerations.

Disclosure Statement

The authors have no conflicts of interest to declare.

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Author Contributions

S.G.: conceptualization, analysis, methodology, writing. A.B. and M.F.: reviewing. A.L.: methodology, reviewing. T.L.: conceptualization, supervision, methodology, validation. C.B.: supervision, methodology, validation.

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9. Discussion générale

Le devenir sous traitement des patients en dialyse péritonéale dépend de leurs caractéristiques qui généralement ne sont pas modifiables. A l'inverse, les caractéristiques ou les pratiques des centres ayant un effet sur le devenir des patients peuvent faire l'objet de changement. Dans ce contexte l'étude de l'effet centre et l'identification de variables centre associées au devenir du patient est une nécessité.

Plusieurs publications récentes montrent que le rôle de l'organisation des centres de traitement sur le devenir du patient est une préoccupation des néphrologues et des équipes soignantes [120].

Nos travaux s'inscrivent dans cette thématique, nous avons pu montrer qu'il existe une hétérogénéité entre les centres de dialyse dans la survenue des infections péritonéales, et de l'échec précoce de la méthode. Nous avons aussi pu montrer que certaines organisations peuvent être modifiées dans l'objectif d'améliorer le devenir du patient en optimisant la ressource. Nos travaux confirment le rôle des équipes infirmières et l'importance des visites infirmières à domicile pour diminuer le risque de péritonite. La mise à disposition de moyens humains minimum pourrait constituer un des critères d'attribution des autorisations de traitement par dialyse donnés aux établissements de santé.

Augmenter la taille des centres pourrait avoir un effet bénéfique sur la survie de la méthode en améliorant l'expérience des centres. Dans ce contexte le regroupement d'activité entre plusieurs établissements pourrait avoir un effet positif sur la survie de la méthode. Nous avons aussi pu observer qu'il existait une disparité entre les centres dans l'utilisation de l'assistance, que l'attribution de l'assistance repose principalement sur l'évaluation de l'infirmière de dialyse ce qui laisse entrevoir des possibilités de rationalisation dans l'utilisation de l'assistance. Compte tenu du coût engendré par l'assistance, des études complémentaires sont nécessaires afin de définir des critères d'attribution. Nos travaux montraient que l'attribution d'une assistance repose essentiellement sur l'évaluation infirmière, les modalités d'évaluation de l'incapacité du patient à être autonome, l'utilisation et la

validation d'outils permettant d'estimer la capacité d'autonomisation du patient est une recherche qui devra être conduite.

9.1. Perspectives et conclusion

Le patient doit pouvoir bénéficier d'une information claire très tôt dans son parcours d'insuffisant rénal. La décision de traitement doit être partagée en tenant compte des attentes et des besoins du patient [121]. La décision partagée est probablement associée à la survie de la méthode de traitement et peut être à une diminution du risque d'infection péritonéale. Etudier les attentes et les préférences du patient concernant la dialyse péritonéale sera un des sujets de mes travaux de recherche ultérieurs.

Il a été montré que les perceptions des professionnels de santé sont différentes de celles des patients. Les objectifs de part et d'autre sont parfois en conflit. Le désir de la plupart des patients est de mener une vie qui a du sens avec le moins de retentissement possible tout en restant le plus possible en bonne santé. Alors que les patients sont davantage préoccupés par leur qualité de vie, les médecins et les soignants semblent plus se concentrer sur les caractéristiques médicales, biologiques [122]. Par exemple, une récente étude néozélandaise a rapporté que les patients préféraient la dialyse à domicile par rapport au centre quand un soutien infirmier important était disponible et si elle permettait une survie plus longue, une amélioration du bien-être et une meilleure flexibilité du traitement [123]. Il est admis que les perceptions et les préférences des patients doivent être étudiées et prises en compte dans les travaux de recherche.

Un article récent [124] rapporte les interrogations de néphrologues à travers le monde sur le potentiel d'augmentation de l'utilisation de la dialyse à domicile si des subventions étaient octroyées aux patients. Les coûts inhérents à la formation, au transport, aux dépenses supplémentaires doivent être pris en charge par les systèmes de santé.

Des mesures incitatives pour les aidants pourraient être proposées pour permettre aux membres de la famille de prendre soin de leur partenaire à la maison.

Les patients dialysés à domicile subissent les coûts liés à la formation, de la consommation supplémentaire d'eau (pour l'HDD) et d'électricité. De plus, le maintien d'une activité professionnelle n'est souvent pas possible ce qui entraine une perte de revenus. En France, lorsque les patients sont autonomes ou assistés par un membre de la famille, ils peuvent bénéficier d'une indemnisation appelée "indemnité compensatrice à tierce personne" (DTP) [125]. Certains patients sont dans une situation sociale précaire, il est possible que certains patients choisissent le traitement autonome pour être éligibles à l'allocation. On ne sait pas si lors de l'information pré-suppléance, les équipes infirmières et médicales évoquent la possibilité de percevoir la DTP et quel pourrait être l'effet de cette information sur le choix de la modalité de traitement. Ainsi étudier les facteurs associés à la préférence des patients dans le choix de la dialyse péritonéale comme traitement de suppléance pourrait peut-être permettre de mieux connaitre les éléments du choix.

La mise sur le marché de dialyseurs compacts, faciles d'utilisation et efficaces doit permettre aux patients en échec de dialyse péritonéale d'être traités par l'hémodialyse à domicile (HDD). L'étude de la préférence du patient pour le traitement à domicile lors du passage de la DP vers l'HD est aussi un sujet de recherche.

La suite de ces travaux consistera à étudier les facteurs associés aux préférences des patients dans le choix de la dialyse péritonéale et la dialyse à domicile en général.

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Autres publications hors thèse

- Viron C, Lobbedez T, Lanot A, Bonamy C, Ficheux M, **Guillouët S**, Bechade C. SIMULTANEOUS REMOVAL AND REINSERTION OF THE PD CATHETER IN RELAPSING PERITONITIS. Perit Dial Int. 2019 May-Jun;39(3):282-288.

- Guilloteau S, Lobbedez T, **Guillouët S**, Verger C, Ficheux M, Lanot A, Béchade C. Impact of Assisted Peritoneal Dialysis Modality on Outcomes: A Cohort Study of the French Language Peritoneal Dialysis Registry. Am J Nephrol. 2018;48(6):425-433.

- Buffet A, **Guillouët S**, Lobbedez T, Ficheux M, Lanot A, Béchade C. Safety of Peritoneal Dialysis after Nonrenal Solid-Organ Transplantation. Perit Dial Int. 2018 Jan-Feb;38(1):37-43.

- Uteza S, Thuillier Lecouf A, Videloup L, Béchade C, Henri P, **Guillouët S**. Etude descriptive des pratiques normandes dans la prise en charge des patients en traitement conservateur. Accepté pour publication dans la revue « Néphrologie & Thérapeutique »

Implication dans la recherche en néphrologie, dialyse, transplantation

Participation en tant qu'investigateur principal ou investigateur associé à différentes études :

- **Etude PANCADIPE** : Utilité du pansement adhésif stérile à l'orifice de sortie du cathéter de dialyse péritonéale

- **Etude SIMFAV** : Intérêt de la formation en simulation procédurale des infirmier(e)s dans la diminution des complications liées à la ponction de fistule artérioveineuse chez des patients hémodialysés chroniques

- **Etude EDDEN** : Évaluation de l'utilisation d'une échelle analogique pour estimer les apports alimentaires, l'EPA, chez les patients hémodialysés

- **Etude DIADIDEAL** : Etude pilote de faisabilité d'une assistance par un(e) infirmier(e) diplômé(e) d'état pour la ponction de fistule en hémodialyse à domicile

Etude de l'effet centre en dialyse péritonéale

Les études regroupées dans cette thèse montrent qu'il existe une hétérogénéité entre les centres de dialyse péritonéale dans la survenue des infections péritonéales et l'échec précoce de la méthode. Nous avons aussi montré que certaines organisations peuvent être modifiées dans l'objectif d'améliorer le devenir du patient en optimisant la ressource.
Nos travaux soulignent le rôle des équipes infirmières et l'importance des visites infirmières à domicile dans la prévention des infections du liquide de dialyse péritonéale. La mise à disposition de moyens humains minimum pourrait constituer un des critères d'attribution des autorisations de traitement par dialyse donnés aux établissements de santé.
Augmenter la taille des centres pourrait avoir un effet bénéfique sur la survie de la méthode en améliorant l'expérience des centres. Dans ce contexte, le regroupement d'activité entre plusieurs établissements pourrait avoir un effet positif sur la survie de la méthode.
Nous avons aussi pu observer qu'il existait une disparité entre les centres dans l'utilisation de l'assistance à domicile par une infirmière pour la réalisation de la dialyse. L'attribution de l'assistance repose principalement sur l'évaluation de l'infirmière de dialyse péritonéale ce qui laisse entrevoir des possibilités de rationalisation dans son utilisation.
L'utilisation et la validation d'outils permettant d'estimer la capacité d'autonomisation du patient est une recherche qui devra être conduite.

Mots clés : Dialyse péritonéale, dialyse péritonéale assistée, pratiques infirmières, effet centre

Center effect in peritoneal dialysis patients

The studies grouped in this thesis show that there is a heterogeneity between the peritoneal dialysis centers in the occurrence of peritoneal infections and the early failure of the method. We have also shown that some organizations can be modified in order to improve the patient's future by optimizing the resource.
Our work highlights the role of nursing teams and the importance of home nursing visits in the prevention of peritoneal dialysis fluid infections. The provision of minimum human resources could be one of the criteria for granting dialysis treatment authorizations given to health facilities.
Increasing the size of the centers could have a beneficial effect on the survival of the method by improving the centers experience. In this context, group activities between several establishments could have a positive effect on the survival of the method.
We also observed that there is a disparity between centers in the use of home assistance by a nurse for dialysis. The allocation of assistance is mainly based on the evaluation of the peritoneal dialysis nurse, which suggests possibilities of rationalization in its use.
The use and validation of tools to estimate the patient's capacity to be treated by self-care peritoneal dialysis is a research that will need to be conducted.

Keywords: peritoneal dialysis, assisted peritoneal dialysis, nursing practices, center effect