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Bulletin de la Dialyse à Domicile

Peritoneal Dialysis Associated Peritonitis Rate – Validation of a Simplified Formula

(Taux de péritonite en dialyse péritonéale : validation d'une formule de calcul simplifiée)

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Note : ce texte est disponible en Français à la même adresse url : <https://doi.org/10.25796/bdd.v4i4.63443>



Résumé

La péritonite est la complication la plus importante de la dialyse péritonéale (DP). Malheureusement, de nombreux centres de DP dans le monde n'enregistrent pas précisément le taux de péritonite, principalement parce qu'ils ne peuvent pas déterminer la durée de soumission au risque en raison de difficultés pour obtenir le nombre de jours-patients à partir des dates individuelles de début et fin de traitement. Nous proposons une méthode de calcul simplifiée de cette durée à partir du nombre de patients en début et fin d'année. Nous avons comparé les mesures de référence des taux annuels de péritonite avec des mesures simplifiées dans les registres australien et néo-zélandais de dialyse et de transplantation (ANZDATA) / registre néo-zélandais (NZ) et le Registre de Dialyse Péritonéale de Langue Française et hémodialyse à domicile (RDPLF). 268 centres de 9 pays avec 4311 années-centres et 110 185 années-patients de suivi ont été modélisés.

La concordance globale est excellente, avec un coefficient de corrélation de concordance de 0,978 (intervalle de confiance à 95 % 0,975-0,980) et un biais moyen (limites de concordance à 95 % tel que défini par Bland et Altman) de 0,002 (-0,138-0,142) dans le registre ANZDATA / NZ. Les statistiques correspondantes sont 0,978 (0,977-0,980) et 0,004 (-0,111-0,119) dans le RDPLF. La concordance est statistiquement plus faible pour les petits centres, bien que la formule simplifiée offre toujours une bonne précision. Il doit cependant être utilisé avec prudence dans les très petits centres (< 5 patients). La méthode simplifiée de calcul du taux de péritonite en PD est précise et permettra à davantage de centres de mesurer, communiquer leur taux de péritonite et de travailler sur leur réduction.

Mots clés : péritonite, dialyse péritonéale, ANZDATA, RDPLF, NZ PD Registry

Summary

Peritonitis is the most important therapy-related complication of peritoneal dialysis (PD). Unfortunately, many PD centers around the world do not measure peritonitis rate, mainly because they cannot ascertain PD patient time-at-risk from "patient flow" - that is, calculating PD patient-days from the date at which patients start and finish PD. We propose a simplified method for calculating PD peritonitis rate from "patient stock" - that is, calculating PD patient-days from the number of prevalent PD patients at a given center at the beginning and end of a year. We compared gold-standard measurements of annual PD peritonitis rates with simplified ones in the Australia and New Zealand Dialysis and Transplant Registry (ANZDATA) / New Zealand (NZ) PD Registry, and Le Registre de Dialyse Péritonéale de Langue Française et hémodialyse à domicile (the RDPLF). A total of 268 centers from 9 countries with 4311 center-years and 110,185 patient-years of follow-up were modelled. Overall agreement is excellent, with a concordance correlation coefficient of 0.978 (95% confidence interval 0.975-0.980) and average bias (95% limits of agreement as defined by Bland and Altman) of 0.002 (-0.138-0.142) in ANZDATA / NZ PD Registry. Corresponding statistics are 0.978 (0.977-0.980) and 0.004 (-0.111-0.119) in the RDPLF. Agreement is statistically poorer for smaller centers, although the simplified formula still provides good accuracy. It should, however, be used with caution in very small (<5 patients) centers. The simplified method of calculating PD peritonitis rate is accurate, and will allow more centers to measure, report, and work on reducing PD peritonitis rates.

Key words : PD peritonitis, peritoneal dialysis, ANZDATA, RDPLF, NZ PD Registry

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INTRODUCTION

Peritonitis is the most urgent and important therapy-related complication to affect peritoneal dialysis (PD). Over the last two decades, improvements in technique and service delivery have reduced the probability of PD peritonitis to an all-time low (1). Despite this excellent progress, PD peritonitis still accounts for up to 5% of all deaths on PD (2). It is the leading priority for improving patient centered outcomes (3, 4). For this reason, PD peritonitis rate is arguably the leading metric for assessment of quality assurance of PD care around the world (5).

Despite the importance of PD peritonitis rate, only a minority of health jurisdictions measure and report PD rates (1). This is largely because of the difficulties that individual PD centers face when calculating PD peritonitis rate. Sometimes, it is that the actual formula that is not well understood. In most cases, however, the difficulties arise from lack of requisite data. PD peritonitis rate is computed as the number of episodes as a function of cumulative time-at-risk. For a given year and cohort, and expressed in episodes per patient-year, the gold-standard computation uses the following formula (6):

$$\frac{\text{Number of PD peritonitis episodes during Year for } N \text{ patients}}{\sum_{\text{Patient } 1}^{\text{Patient } N} \left(\frac{\text{Days on PD during Year}}{365.25} \right)} \quad \text{Eq 1}$$

In most PD centers, recording and recalling number of PD episodes over a given period of observation is not difficult. However, many PD centers around the world do not have systems that accurately record “patient flow” - that is, the date when patients start and finish PD. Even when they do have access to such data, many do not have the resources to manually retrieve it and calculate cumulative time-at-risk for their cohort.

We propose a simplified calculation that is easier to compute in a practical sense. This simplification replaces the time-at-risk denominator in the gold-standard formula above. The simplified time-at-risk denominator is calculated from “patient stock” - that is, the number of patients in a center at any point in time, a more easily accessible statistic for most PD centers (7):

$$\frac{\text{Number of PD peritonitis episodes during Year for a given center}}{\left((N_{\text{Year Start}} + N_{\text{Year Finish}}) / 2 \right)} \quad \text{Eq 2}$$

The equivalence between the gold-standard and simplified formulae relies on a key assumption: namely, that patients start and finish PD at a uniform rate throughout the year (that is, at random).

In this paper, we explore the accuracy of the simplified formula in two databases. The first is Australia and New Zealand Dialysis and Transplant Registry (ANZDATA) / New Zealand (NZ)

PD Registry. The second is Registre de Dialyse Péritonéale de Langue Française et hémodialyse à domicile (RDPLF).

METHODS

Study Design

We performed an observational cohort study to measure agreement between gold-standard annual PD peritonitis rates and those estimated using the simplified formula. The National (NZ) Health and Disability Ethics Committee (IORG0000895) approved the study protocol, and waived the need for patient consent under the provisions for observational research.

Patient Participants and Data Source

The ANZDATA Registry collects data on all kidney failure (KF) patients from every dialysis centre in Australia and New Zealand. KF patients are defined as those with a diagnosis of chronic kidney disease, in whom renal replacement therapy is intended as an indefinite treatment. Data on PD peritonitis in Australia and New Zealand has been collected since 2004 (in NZ, directly by ANZDATA until June 2021, but through data linkage with the NZ PD Registry thereafter). The RDPLF collects data on corresponding patients from every dialysis centre in France, as well as larger PD centres in Algeria, Francophone Belgium, the Kingdom of Morocco and Southern Provinces, Luxembourg, Francophone Switzerland, and Tunisia. PD peritonitis has been collected since the registry's inception in 1986. Details of the structure and methods of all the registries are reported elsewhere (www.anzdata.org.au, www.pdregistry.org.nz, <https://rdplf.org/> (8-11)).

We created a study cohort of KF patients treated with PD. In ANZDATA / NZ PD Registry, this cohort comprised children and adults over a period of observation starting on 1-Jan-2004. Prevalent PD patients at the start of this period of observation were included, and these and any incident PD patients were followed through until 31-December-2019. In the RDPLF, the study cohort comprised corresponding adult patients between the dates of 1-Jan-2000 and 31-December-2020.

Primary Exposure and Outcome Variables

The primary exposure in this study is PD peritonitis, as recorded in the respective registries based upon the opinion of the treating physician / PD team. Gold-standard annual PD peritonitis rates were calculated using Equation 1 above, and estimated annual PD peritonitis rates from Equation 2.

For ANZDATA, the attributed center of PD treatment for each patient-episode was the one at PD inception, since only a very small proportion of PD patients change centers in Australia and New Zealand. For the RDPLF, episodes are split by center at source, and the attributed center of PD treatment for each patient-episode is therefore time-varying.

Data Measurement and Quantitative Variables

We also used patient characteristics in our models, to identify any effect modification on concordance statistics arising from variation in patient case mix between centers. The clinical and demographic characteristics used in ANZDATA / NZ PD Registry models were: country, age at PD inception, PD sub-modality (automated PD [APD], continuous ambulatory PD [CAPD]), gender, ethnicity (Caucasian / other, Aboriginal or Torres Strait Islander, Asian, NZ Maori, Pacific peoples), primary kidney disease (diabetic nephropathy, ischemic / hypertensive nephropathy, glomerulonephritis, other), late referral for nephrology pre-dialysis care (<3 months before dialysis inception), and rurality (living in a major city, living in a regional town or remotely). Corresponding characteristics in RDPLF models were: country, age at PD inception, PD sub-modality (APD, CAPD), gender, diabetes mellitus (none, type 1 or type 2), and medical co-morbidity (Charlson co-morbidity index [CCS](12)).

Statistical Methods

Agreement between gold-standard and estimated annual PD peritonitis rates were assessed using concordance statistics. The relationship-scale framework underpins Lin's implementation of the concordance correlation coefficient (CCC), which combines measures of both precision (Pearson correlation coefficient) and accuracy (the bias-correction factor) to determine how far the observed data deviate from the line of perfect concordance (that is, the line at 45 degrees on a square scatterplot). Lin's CCC increases in value as a function of the tightness of the data about its reduced major axis (the precision of the estimation) and the nearness of the data's reduced major axis to the line of perfect concordance (the accuracy of the estimation) (13-16). The data-scale framework underpins Bland and Altman's limits-of-agreement (LoA) procedure, which is complementary to the relationship-scale approach (17).

We tested for effect modification of by comparing concordance statistics between subgroups of centers. For each year in which annual peritonitis rates were calculated, subgroups of centers were created based on their patient case mix. For example, in Australia and New Zealand centers during 2004, 2 subgroups of centers were created according proportion of their patients who live either regionally or remotely (>median for all centers in 2004 versus < median). We then checked for significant differences in Lin's CCC between each subgroup. In ANZDATA, we assessed for effect modification by the following factors: country (Australia versus New Zealand), pediatric [< 18 years] versus adult [\geq 18 years]), size of PD population, proportion of patients on APD, proportion of males, proportion with indigenous or Pacific ethnicity, proportion with high-risk primary kidney disease (ischemic or diabetic nephropathy), late referral for nephrology pre-dialysis care, and rurality. In RDPLF, the corresponding assessments involved: country (France, Algeria, Francophone Belgium, the Kingdom of Morocco and Southern Provinces, Luxembourg, Francophone Switzerland, and Tunisia), size of PD population, mean age of patients at PD inception, proportion of patients on APD, proportion of males, proportion of patients with diabetes mellitus, and presence and extent of medical co-morbidity (> median CCS versus < median CCS).

Comparisons of CCC between subgroups were made using a z-test with a null hypothesis that the difference between CCC was of zero. For subgroups of more than two, comparisons were made by ANOVA (18).

In all analyses, an error trap was utilized to exclude those centers with an annual PD peritonitis rate > 3 episodes per patient-year.

RESULTS

Descriptive Data

The ANZDATA dataset comprised 80 PD centers from 2 countries with a total of 1085 center-years and 48,256 patient-years of follow-up. There were 19,669 episodes of peritonitis over this period. Summary statistics of center characteristics (or more accurately, summary statistics of each center-year characteristics) are shown in *Table I*. The RDPLF dataset comprised 188 centers from 7 countries (*Table II*) with a total of 3226 center-years and 61,929 patient-years of follow-up. There were 22,482 episodes of peritonitis over this period.

Three center-years from ANZDATA were excluded through the error trap, with annual PD peritonitis rates of 3.2, 3.4 and 11 episodes per patient-year at respective centers. During those years, the centers had patients stock and flow of only between 0-2 PD patients. Four center-years from the RDPLF were excluded through the error trap, with annual PD peritonitis rates of 3, 4, 10, and 12 episodes per patient-year at respective centers. During those years, the centers had stock and flow of only between 0-1 PD patients.

Table I: Summary characteristics of centers in Australia and New Zealand 2004 - 2019

		N	Median	P25	P75
PD centers	Total	80			
	New Zealand	12			
	Australia	68			
Total center-years		1085			
Patient	Stock (N @ end of year)		27	10	60
	Flow (total N during year)		39	16	88
Age (years)	@ PD start		58.18	55.04	60.72
Gender	Male		0.58	0.51	0.65
	Female		0.42	0.35	0.49
Residential status*	Major city		0.67	0	0.89
	Regional		0.29	0.09	0.75
	Remote		0	0	0.04
Referral for RRT*	Late		0.17	0.12	0.25
	Timely		0.83	0.74	0.87
Ethnicity*	Caucasian / other		0.80	0.62	0.9
	Aboriginal / Torres Strait Islander		0	0	0.06
	Asian		0.07	0	0.17
	NZ Maori		0	0	0.03
	Pacific People		0	0	0.04
Primary kidney disease*	Diabetic		0.29	0.19	0.37
	Hypertensive / ischaemic		0.13	0.07	0.18
	Glomerulonephritis		0.25	0.20	0.32
	Other		0.29	0.22	0.39
Modality*	APD		0.57	0.36	0.75
	CAPD		0.43	0.25	0.64

* proportion of patients in each center-year with the characteristic

Table II : Summary characteristics of centers in the RDPLF 2000-2020

	N		Median	P25	P75
PD centers	Total	188			
	Algeria	1			
	Belgium	17			
	France	155			
	Luxembourg	1			
	Morocco and Southern Provinces	5			
	Switzerland	3			
	Tunisia	6			
	Total center-years		3226		
Patient	Stock (N @ end of year)		16	8	26
	Flow (total N during year)		24	13	38
Age (years)	@ PD start		66.25	61.02	70.52
Gender*	Male		0.59	0.5	0.67
	Female		0.41	0.33	0.5
Diabetes mellitus			0.3	0.2	0.4
Charlson			5.78	4.85	6.5
Modality*	APD		0.35	0.21	0.52
	CAPD		0.65	0.48	0.79

Main results

Overall, the average agreement between gold-standard and estimated annual PD peritonitis rates were high, as assessed using concordance statistics and Bland and Altman analysis. For ANZDATA / NZ PD, the CCC was 0.978 (95% confidence interval [CI] 0.975-0.980) and average bias (95% LoA) 0.002 (-0.138-0.142). For the RDPLF, the corresponding statistics were 0.978 (0.977-0.980) and 0.004 (-0.111=0.119), respectively.

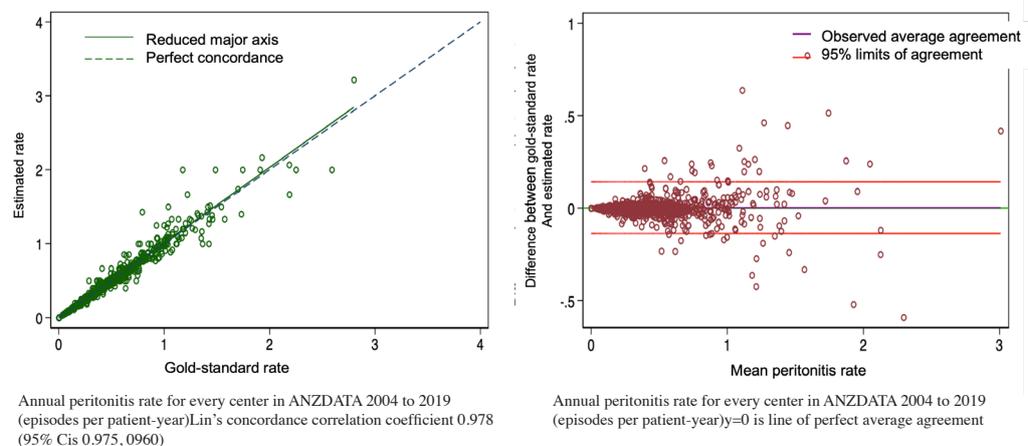


Figure 1. Graphical description of agreement between gold-standard and estimated PD annual peritonitis rates for every center in ANZDATA 2004-2019

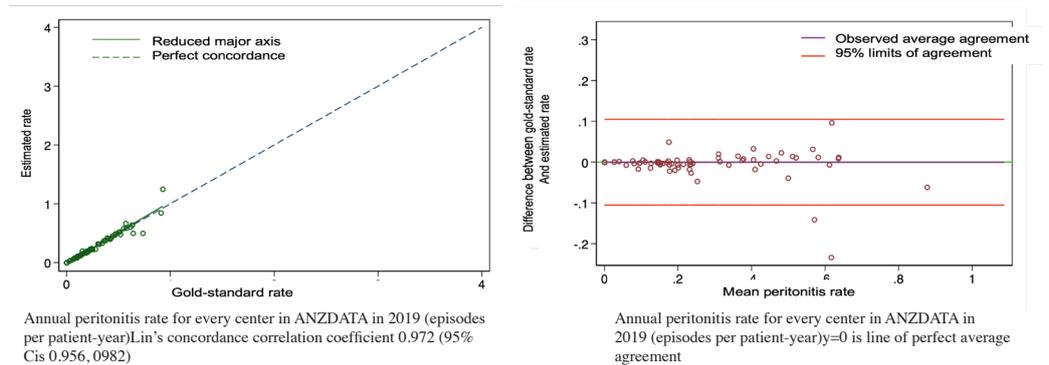


Figure 2. Graphical description of agreement between gold-standard and estimated PD annual peritonitis rates for every center in ANZDATA during the latest year available (2019)

Graphical descriptions of relationship-scale and data-scale agreement for ANZDATA are shown in Figure 1 for the entire period of observation and in Figure 2 for the last year (2019) of available data. Table III shows the results of testing within subgroups of centers defined by their patient case mix. The strongest effect modifier was found in center size, with poorer agreement between gold-standard and estimated rates in smaller centers. There was statistically poorer agreement in centers that were pediatric, located in Australia, with lower proportions of patients of Indigenous or Pacific ethnicity, and higher proportions of people on APD. However, these characteristics also correlated with center size: pediatric versus adult (mean PD stock per center of 7 versus 50 patients), Australia versus New Zealand (40 versus 70), lower proportion Indigenous / Pacific ethnicity versus not (37 versus 58), higher proportion of APD versus not (31 versus 59). Statistical differences in agreement between these subgroups were not present when assessed within the same strata of center size. Notwithstanding, these are still center characteristics indicative of situations associated with poorer concordance between gold-standard and estimated rates of PD peritonitis rates.

Table III. Effect modification of concordance statistics in ANZDATA centers according to their casemix

Characteristics		Lin's CCC (95% Cis)	P-value of two-way interaction
Center size	> median number of patients	0.996 (0.995-0.997)	<0.0001
	< median number of patients	0.972 (0.966-0.976)	
Age	Adult	0.980 (0.978-0.983)	0.03
	Pediatric	0.967 (0.954-0.976)	
Country	Australia	0.976 (0.972-0.979)	<0.0001
	New Zealand	0.994 (0.992-0.995)	
Indigenous / Pacific peoples	> median proportion	0.982 (0.979-0.985)	0.0003
	< median proportion	0.972 (0.967-0.976)	
Major city residents	$\geq 50\%$ of patients	0.975 (0.970-0.978)	0.77
	<50% of patients	0.976 (0.970-0.981)	
High-risk primary kidney disease (diabetic / ischemic)	> median proportion	0.975 (0.970-0.979)	0.07
	< median proportion	0.980 (0.977-0.983)	
APD versus CAPD	> median proportion on APD	0.986 (0.983-0.988)	<0.0001
	< median proportion on APD	0.973 (0.968-0.977)	

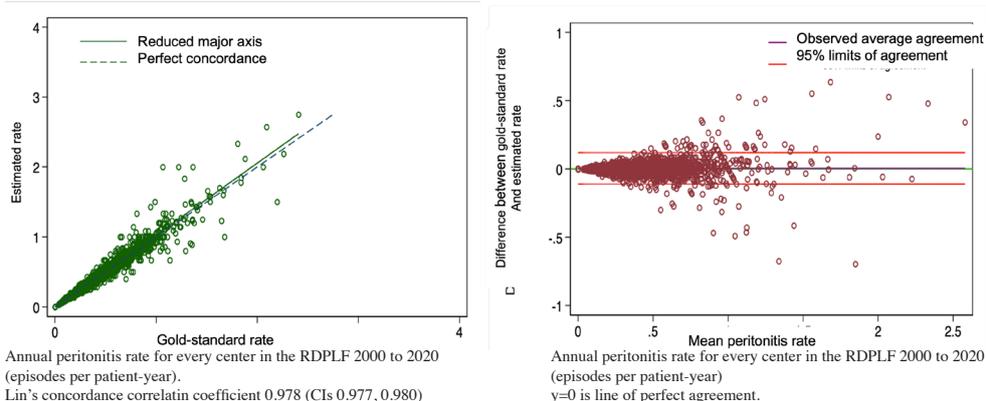


Figure 3. Graphical description of agreement between gold-standard and estimated PD annual peritonitis rates for every center in the RDPLF 2000-2020

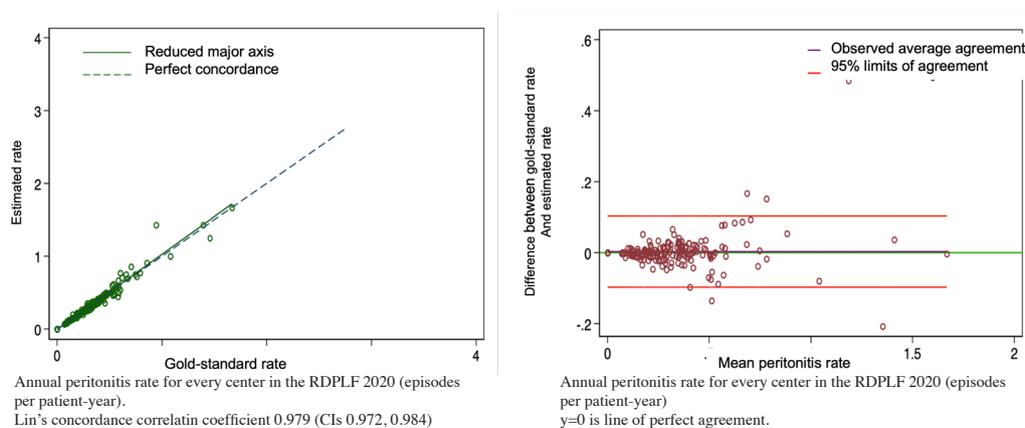


Figure 4. Graphical description of agreement between gold-standard and estimated PD annual peritonitis rates for every center in the RDPLF during the latest year available (2020)

Table IV: Effect modification of concordance statistics in the RDPLF centers according to their casemix

Characteristics		Lin's CCC (95% CIs)	P-value of two-way interaction
Center size	> median number of patients	0.992 (0.991-0.993)	<0.0001
	< median number of patients	0.973 (0.970-0.976)	
Age	> median	0.976 (0.974-0.978)	0.0001
	< median	0.981 (0.979-0.982)	
Country	Algeria	n/a	<0.0001
	Belgium	0.976 (0.970-0.981)	
	France	0.979 (0.978-0.981)	
	Luxembourg	0.974 (0.876-0.995)	
	Morocco and Southern Provinces	0.933 (0.894-0.958)	
	Switzerland	0.973 (0.953-0.985)	
Charlson Comorbidity Index	> median score	0.971 (0.968-0.974)	<0.0001
	< median score	0.984 (0.982-0.986)	
APD versus CAPD	> median % on APD	0.981 (0.979-0.983)	0.001
	< median % on APD	0.976 (0.974-0.978)	

Graphical descriptions of relationship-scale and data-scale agreement for the RDPLF are shown in *Figure 3* for the entire period of observation and in *Figure 4* for the last year of available data (2020). *Table IV* shows the results of testing within subgroups of centers defined by their patient case mix. Like ANZDATA, the strongest effect modifier in the RDPLF was found in center size, with again poorer agreement between gold-standard and estimated rates in smaller centers. There was statistically poorer agreement in centers with a number of other characteristics, although like ANZDATA some of these characteristics also tended to correlate with center size: older versus younger (mean PD stock per center of 17 versus 21 patients), higher proportion of APD versus not (20 versus 18). The top three countries with the highest concordance statistics were also those with the largest mean PD patient stock per center (Tunisia 39, France 19, Belgium 16).

Table V: Casemix of center-years with differences between gold-standard and estimated peritoneal dialysis (PD) peritonitis rates outside Bland and Altman 95% limits of agreement (LoA)

Characteristics		Outside 95% LoA	Within 95% LoA	P-value
ANZDATA / NZ PD Registry				
N of center-years		51	1034	
Number of patients	beginning of year	4 (1-6)	28 (12-63)	<0.0001
	end of year	4 (1-6)	29 (13-64)	<0.0001
Age	years	50 (6.9-57.7)	58.3 (55.5-60.8)	<0.0001
Major city residents	Proportion	0.65 (0-0.86)	0.67 (0-89)	0.1
High-risk primary kidney disease (diabetic / ischemic)	Proportion	0 (0-0.63)	0.45 (0.35-0.53)	0.002
Automated peritoneal dialysis	Proportion	0.78 (0.46-1)	0.56 (0.36-0.75)	0.04
Gold-standard PD peritonitis rate	per patient-year	1.02 (0.66-1.4)	0.36 (0.21-0.53)	<0.0001
Estimated PD peritonitis rate	per patient-year	1.17 (0.86-1.67)	0.36 (0.21-0.53)	<0.0001
RDPLF				
N of center-years		112	3114	
Number of patients	beginning of year	5 (2-8)	16 (8-26)	<0.0001
	end of year	5 (3-9)	16 (6-27)	<0.0001
Age	years	67.7 (60.4-72.4)	66.2 (61.1-70.5)	0.8
Charlson Comorbidity Index		6.0 (4.3-6.9)	5.8 (4.9-6.5)	0.7
Diabetes mellitus	Proportion	0.32 (0.16-0.45)	0.3 (0.2-0.4)	0.31
Automated peritoneal dialysis	Proportion	0.33 (0.15-0.52)	0.35 (0.21-0.52)	0.42
Gold-standard PD peritonitis rate	per patient-year	0.91 (0.67-1.23)	0.3 (0.16-0.47)	<0.0001
Estimated PD peritonitis rate	per patient-year	0.83 (0.66-1.12)	0.3 (0.16-0.47)	<0.0001

Table V compares center-years falling outside Bland and Altman 95% limits of agreement with those falling inside. Taking the ANZDATA and RDPLF data together, it can be concluded that

lack of agreement is greatest for centers with less than 5 patients, and does not depend on sub-modality of PD treatment, rurality, or patient age or co-morbidity. In centers with less than 5 patients, the directional relationship between gold-standard and estimated PD peritonitis rate is not predictable: in ANZDATA, estimated rates were consistently higher than gold-standard ones, and in RDPLF, the opposite.

DISCUSSION

In this paper, we show that annual PD peritonitis rate can be estimated fairly accurately using the number of episodes of PD peritonitis for a given center over a given observation period, as well as their “patient stock” (i.e., patients on PD) at the at the start and end of the period). This avoids the need for cumbersome collection and computations based on their “patient flow” (i.e., number of prevalent patients-days during the year). We show that this estimation is good enough for almost every type of PD center, although it is most accurate in larger ones. The greatest lack of agreement is seen with very small centers with 5 or less patients. Notwithstanding, concordance was still very good in most smaller centers in both ANZDATA (Lin’s CCC of 0.972 in centers averaging 12 PD patients at year-end) and the RDPLF (Lin’s CCC of 0.973 in centers averaging 8 PD patients at year end). The very small centers in both ANZDATA and the RDPLF generally had 3-4 fold more PD peritonitis than average, and it can be argued that under- or overestimation of gold-standard PD peritonitis rate by 10-20% either way is not going to jeopardize wise decision-making in a meaningful way.

Difficulties in monitoring PD peritonitis rate are unhelpful for centers that want to identify or address issues with the quality of their PD care, and an impediment to increased uptake of PD. Improvements in PD technology, exchange procedures and patients training protocols have all been helpful in reducing PD peritonitis rates, but this complication is still an important one and responsible for almost all therapy-related deaths. The ability to monitor, compare and report PD peritonitis rates between centers is a fundamental requirement to reduce PD peritonitis rates further.

In a recent systematic review, it was determined that only a minority of health jurisdictions capture PD peritonitis rates in a systematic way (1). This was mainly found to be a problem in emerging economies and not so common in developed countries or those with mature PD programs. This limitation appears to arise in 2 main settings. First, it can be due to lack of information systems for storage and recall. Second, it can be due to workload or staffing changes that leave centers under-resourced for both clinical care and also clinical quality. Naturally, the former is prioritized at the cost of compromise to the latter. In both cases, the retrieval and processing of information become untenable, especially when it involves tracking detailed metrics like time-at-risk on PD.

CONCLUSION

We recommend that the gold-standard formula is used under certain circumstances. First, if there is a strong and unbalanced pattern to starting and discontinuation of PD at a center (e.g. when a center is rapidly losing patients or gaining them over the year in a non-linear manner). Secondly, any PD peritonitis rate that is close to clinical threshold of 0.5 PD peritonitis episodes per patient-

year with the estimated formula ought to be checked with the gold-standard one – the simplified formula should be used with a view to increasing the access of patients to appropriate care, not to limit it. Thirdly, in centers with less than 5 patients the gold-standard formula should be used. In all of these three settings, if there are exceptionally high PD peritonitis rates then the use of the simplified formula will probably be sufficient to guide good clinical decision-making. Outside of these limitations, the simplified formula is an adequate substitute for the gold standard one.

Finally, there is some further work to be done to test the formula over shorter time period (e.g. monthly PD peritonitis rates), and also in centers with wide variations in PD peritonitis rate. In the meantime, we hope that this formula allows for wider monitoring and clinical quality assurance to prevent and address high rates of this complication.

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CONFLICT OF INTEREST

The authors declare no conflict of interest for this article.

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