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Predictors of peritoneal dialysis associated peritonitis; application of the zero-inflated negative binomial model

Shahrokh Ezzatzadegan Jahromi[1], Faisal Ahmed[2], Saeedeh Pourahmad[3,4,5], Jamshid Roozbeh[1], Iraj Najafi[6], Vahid Ebrahimi[1,4,5*]

[1]Shiraz Nephro-Urology Research Center, Shiraz University of Medical Sciences, Shiraz, Iran
[2]Department of Urology, Shiraz University of Medical Sciences, Shiraz, Iran
[3]Bioinformatics and Computational Biology Research Center, Shiraz University of Medical Sciences, Shiraz, Iran
[4]Department of Biostatistics, School of Medicine, Shiraz University of Medical Sciences, Shiraz, Iran
[5]Colorectal Research Center, Shiraz University of Medical Sciences, Shiraz, Iran
[6]Department of Nephrology, Tehran University of Medical Sciences, Tehran, Iran

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ABSTRACT

Background: Peritonitis is the main cause of morbidity and dropout from peritoneal dialysis (PD) program.

Objectives: We aimed to determine risk factors predisposing to PD-associated peritonitis.

Patients and Methods: As a retrospective cohort research, on 235 PD individuals with 4277 patient-months of follow up, 170 episodes of peritonitis was reported in 93 patients. Data were extracted from medical records using a template. Standard as well as zero-inflated negative binominal regression was used to model the association between patients' characteristics and the peritonitis rate. Cox-proportional hazard (PH) adjusted model was used to determine the effect of factors on the peritonitis-free survival.

Results: With a mean (SD) body mass index (BMI) of 18.7(3.4) kg/m2, 109 (46.4%) of them were male. With a median (95% CI) follow-up time of 19 (16 to 36) months, the rate of peritonitis was 0.48 episode per patient-year. The most common micro-organism detected was coagulase-negative staphylococci (n=54; 31.7%). The only variable which was associated with a higher rate of peritonitis was BMI (rate ratio [RR]: 1.07; 95% CI 1.01 to 1.14; *P* value=0.031). Comparing to patients with lower education, patients with higher than elementary school of education had higher peritonitis-free survival (with hazard ratio [HR]=0.51; 95%CI 0.33-0.79, *P* value=0.003) and higher chance of having no peritonitis [odds ratio (OR):1.97; 95% CI 1.08 to 3.59; *P* value=0.029].

Conclusions: Peritonitis is still a major concern in PD patients. BMI was a risk factor for higher peritonitis rate. Higher education level was associated with lower peritonitis-free survival and higher chance of having no peritonitis.

Implication for health policy/practice/research/medical education:
In a retrospective study on 235 peritoneal dialysis patients with 4277 patient-months of follow up, with 170 episodes of peritonitis in 93 patients, we found body mass index was a risk factor for higher peritonitis rate.

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Original Article

1. Background

Renal replacement therapy is performed by several methods around the world, including renal transplantation, intermittent hemodialysis (HD), and peritoneal dialysis (PD) (1). There are studies which have demonstrated the advantages of PD over HD and have introduced PD as the first-line established choice for renal replacement (2,3).

The use of PD and its different modalities vary in different countries and is reported to have a significant difference between developed and developing countries (4). It has been reported that PD patients represent around 11% of all dialysis patients worldwide (4), but

*Corresponding author: Vahid Ebrahimi, Email: ebrahimiv@sums.ac.ir

its administration depends on various factors, such as health care system, socio-economic status, educational factors, clinical experience, and patient factors (5). For example, in Iran, PD has been neglected because of the easy accessibility and reasonable cost of HD, available technique and experience for renal transplantation, and the availability of donors (6).

Despite its advantages, most patients cannot maintain PD for a long-time, as it has some limitations and complications including bleeding, pain, cuff extrusion, catheter-related complications (7), which may cause complications, death, and even switching to HD, or renal transplantation (8).

Peritonitis is a serious concern in patients undergoing PD. Its prevalence is variable among different centers and has declined over the years due to modifications in connectors and catheters, implantation techniques, and treatment protocols (9). Although several studies have identified some predisposing factors such as age, gender, race, co-existing diseases such as type 2 diabetes mellitus, current smoking, nasal carriage of *Staphylococcus aureus*, and hypoalbuminemia (10-12), recent review studies suggest the need for further studies to determine detailed information of causative micro-organisms, risk factors, and proper intervention (13).

2. Objectives

Since no studies have assessed of the risk factors predisposing to peritonitis in patients on PD in Iran and even in the Middle East, we aimed to determine the prevalence and incidence of PD-associated peritonitis (PDAP) and the risk factors predisposing patients to peritonitis.

3. Patients and Methods

All the patients undergoing chronic PD from April 2006 to April 2012 who were referred from health care centers of south provinces of Iran to Emam-Reza clinic PD center, Shiraz, Iran and who were on PD for at least 30 days were included (total eligible sample size; 235). All patients were on chronic ambulatory peritoneal dialysis (CAPD) with glucose-containing solutions. We used two-cuff, swan-necked, coiled catheters with mupirocin topical ointment for exit-site care. The patients were from south provinces of Iran.

Data including age, gender, body mass index (BMI), educational level, underlying disease, and duration of PD were extracted from medical records using a template. Those patients who had positive nasal culture for *S. aureus* (before starting PD) underwent eradication treatment with mupirocin nasal ointment and were considered as nasal *S. aureus* carriers in this study. The information including the frequency of peritonitis, the fluid culture results, and the timing of peritonitis episodes were recorded. Diagnosis of peritonitis was made according to a generally accepted criteria (9) based on having two of the three following criteria; **a)** abdominal pain and/or cloudy PD fluid, **b)** white blood cell count greater than 100 per microliter with more than 50% of polymorphonuclears in the effluent fluid, **c)** positive fluid culture. PD effluent culture was performed by injection of 10 mL of the fluid into blood culture bottles without prior centrifugation (14).

3.1. Ethical approval

The protocol of the study was approved by the Ethics Committee of Shiraz University of Medical Sciences (SUMS- IRIB code: 90-01-01-3532). Because the data were analyzed anonymously, no informed consent was given. The current study was performed according to the Institutional Committee for the Protection of Human Subjects, which was adopted by the 18th World Medical Assembly, Helsinki, Finland and its later amendments. Written informed consents were obtained from the parents of both patients and controls. The present article was extracted from the thesis written by Faisal Ahmed, which was financially supported by Shiraz University of Medical Sciences (grant # 3532-01-01-90).

3.2. Statistical analysis

Standard statistical approaches (two-sample *t* test and chi-square test) were employed to compare the distribution of variables between patients with and without peritonitis. Non-parametric Kaplan–Meier (KM) method was applied to estimate the probability of peritonitis-free survival by considering time to the first peritonitis episode (in months) as an outcome. In order to determine the effect of factors on the peritonitis-free survival, we used semi-parametric Cox-proportional hazard (PH) adjusted model. For finding a parsimonious model, we applied backward elimination of the factors with highest *P* values, $P > 0.2$, one by one. Variable selection was also based on the importance of a factor.

Standard negative binomial (NB) regression model which is used for modeling count variables, usually for over-dispersed count outcome variables, was used to determine the risk factors of peritonitis and model the association between patients' characteristics and the peritonitis rate (the number of peritonitis per year). Due to the high number of patients with zero peritonitis rates (>60% of the patients), we applied zero-inflated negative binomial (ZINB) regression model as well (15, 16). In fact, ZINB regression model calculates the change in the odds of having no peritonitis if a change occurs in a variable (for continuous variables) or change occurs in the category of a variable (for categorical variables). We

used the Vuong test to determine if the result of the ZINB differs from the standard NB.

Stata version 14.2 software was used for doing the statistical analysis. *P* value < 0.05 was considered statistically significant.

4. Results

A total of 235 patients with mean (SD) age of 48.5 (16.5) years (range; 17-89 years) with a median (95%CI) follow-up time of 19 (16 to 36) months (range; 1-72 months) were included. With a mean (SD) BMI of 18.7 (3.4) kg/m^2 (range; 11.2-31.1 kg/m^2), 109 (46.4%) of them were male. In terms of the causes of primary renal disease, diabetes mellitus (n=77; 32.8%) was the most common, followed by hypertension (n=47; 20.0%), polycystic kidney disease (n=11; 4.7%), and chronic glomerulonephritis (n=8; 3.4%).

Among all the recruited patients, 93 (39.6%) were complicated with peritonitis, including 39 (41.9%) men and 54 (58.1%) women with a total of 170 peritonitis episodes. Regarding the number of episodes, 50 (53.8%) patients had one episode of peritonitis, 23 (24.7%) had two episodes and 20 (21.5%) patients had three or more episodes. With a total follow-up time of 4277 patient-months and after exclusion of relapsing or recurrent peritonitis episodes, defined as the peritonitis occurred within the 4 weeks of completion of previous episode treatment with the same or different organism, the peritonitis rate was one episode per 25.2 patient-months (0.48 episodes per year).

While culture results from 27 (15.9%) episodes were not available, the result of 37 (25.8%) of the performed samples was negative. The most common micro-organism isolated was coagulase-negative staphylococci (n=54; 31.7%).

As demonstrated in Table 1, patients with peritonitis had significantly higher rate of hypertension (as an underlying disease) (26.9% versus 15.5%, *P*=0.033) and lower educational level (below elementary school 46.2% versus 28.9%, *P*=0.007). Mean of BMI had significantly higher value in peritonitis group as well (19.2 kg/m^2 versus 18.2 kg/m^2, *P*=0.044). There was no significant difference in the distribution of age, gender, history of previous HD, and nasal carrier status for *S. aureus* between patients with and without peritonitis was existed (Table 1).

In terms of the timing of the occurrence of peritonitis, the median (95%CI) time of the first episode of peritonitis was 7 (6 to 11) months (ranging from 1-42 months) and all episodes was 11 (9 to 12) months (ranging from 1-54) after starting PD. Figure 1 shows the peritonitis-free survival curve of the study population which indicates that no peritonitis occurred for 50% of the patients up to the 19th month of follow up. As shown in Figure 2, patients with lower levels of education (lower than elementary school) had lower peritonitis-free survival (Log-rank statistic *P* value=0.003). Considering peritonitis-free survival, the Cox PH model using Breslow method indicated that the only variable associated with lower risk of peritonitis was higher education level (with hazard ratio [HR]=0.51; 95%CI, 0.33-0.79, *P*=0.003) (Table 2).

The association between patients' characteristics and the peritonitis rate analyzed by standard NB regression analysis as well as ZINB regression analysis with logit link (Table 3). The standard NB regression findings demonstrated that the only variable associated with a higher rate of peritonitis were BMI (rate ratio [RR]: 1.07;

Table 1. Comparing the characteristics of the patients with and without peritonitis (N = 235)

Characteristic	Patients with peritonitis (n=93), No. (%)	Patients without peritonitis (n=142), No. (%)	*P* value
Male sex	39 (41.9)	70 (49.3)	0.269
Age			0.110
≤55 years	56 (60.2)	97 (68.3)	
>55 years	37 (39.8)	45 (31.7)	
BMI (kg/m^2)	19.2±3.5[a]	18.2±3.4[a]	0.044[b]
Previous hemodialysis	39 (41.9)	68 (47.9)	0.370
Staphylococcus aureus nasal carrier	54 (58.1)	66 (46.5)	0.183
Below elementary school of education	43 (46.2)	41 (28.9)	0.007[b]
Primary renal disease			
Diabetes mellitus	35 (37.6)	42 (29.6)	0.198
Hypertension	25 (26.9)	22 (15.5)	0.033[b]
Polycystic kidney disease	3 (3.2)	8 (5.6)	0.393
Chronic glomerulonephritis	2 (2.2)	6 (4.2)	0.391
Unknown etiology	28 (30.1)	64 (45.1)	0.022[b]

[a] Values are shown as mean ± standard deviation.
[b] *P* value < 0.05 is considered significant.

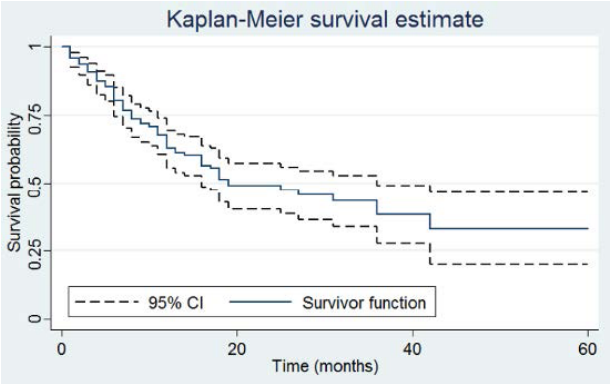

Figure 1. Kaplan-Meier survival estimates plot along with confidence interval of study population peritonitis-free survival (Median survival time equals to 19 months; 95% CI, 16 months to 36 months).

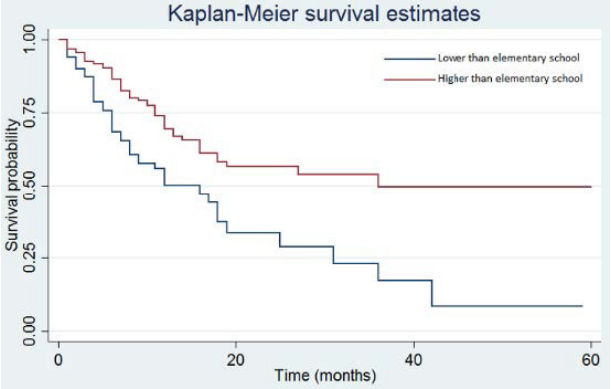

Figure 2. Kaplan-Meier survival estimates of peritonitis-free survival for two categories of educational level (Log-rank statistic *P* value = 0.003).

95% CI 1.01 to 1.14; *P*=0.031). On the other hand, gender, underlying diseases such as DM, history of HD before PD, and age were not found to be associated with a higher rate of peritonitis. The ZINB regression analysis showed that the education level is the only variable linked to zero peritonitis rate, i.e. patients with higher than elementary school of education have higher chance of having no peritonitis comparing to patients with lower than elementary school of education [odds ratio (OR):1.97; 95% CI 1.08 to 3.59; *P*=0.029]. The Vuong test results were significant (*P*<0.05), recommending to report findings with the ZINB analyses (Table 3).

5. Discussion

This study showed that lower educational level was associated with earlier occurrence and higher BMI was linked to higher rate of PD associated peritonitis. Peritonitis, which is a major concern in the patients on PD, has been reported to involve nearly 40% of the PD population in our study with a rate of one episode per

Table 2. The Cox-proportional hazards (PH) results using Breslow method for variables influencing peritonitis-free survival

Patients' characteristics	HR	95% CI	*P* value
Sex			
Male	1	-	-
Female	1.11	0.72 to 1.72	0.637
Age			
≤55 years	1	-	-
>55 years	0.78	0.50 to 1.22	0.278
Body mass index (BMI)	1.05	0.98 to 1.11	0.154
Education			
Lower than elementary school	1	-	-
Higher than elementary school	0.51	0.33 to 0.79	0.003[a]
DM			
No	1	-	-
Yes	0.96	0.62 to 1.52	0.874
HD before PD			
No	1	-	-
Yes	0.93	0.62 to 1.42	0.756

Abbreviations: CI, confidence interval; DM, diabetes mellitus; HD, hemodialysis; HR, hazard ratio; PD, peritoneal dialysis.
[a] *P* value <0.05 is considered significant.

25.20 patient-months (0.48 per year) which is less than but close to the International Society for Peritoneal Dialysis (ISPD) guideline recommendation of 0.5 episode per year(17). Other Iranian studies have also reported a similar rate. Rahimian and colleagues reported the prevalence of PDAP at 41.6% with higher incidence in women (57.6%) in Yazd, Iran in 2008 (18), which was consistent with our results, however, the rate of peritonitis was not reported. Najafi and colleagues reviewed the 12 years data of peritonitis in 27 Iranian centers and reported a rate of one episode in 34.1 patient-months which is lower than our study (19). Lobo et al found a, 42.7% PDAP prevalence with a rate of 28.4 patient/episode/month in a Brazilian center which was also close to our statistics (11).

The majority of studies reported the average peritonitis rate in the range of every 26 to 34 months for each patient (10,11,19-21). Although some studies have reported approximately the same incidence to our study, the diversity in PDAP rate might be due to the difference in patients' characteristics and definitions of peritonitis. Unlike our study, most of the others considered not only CAPD patients but also patients on automated PD (10, 11,19-21).

No micro-organism was detected in 25.8% of the performed cultures which is higher than what ISPD guideline recommended and could be explained by inoculation of low amount of effluent on blood-culture

Table 3. The association between patients' characteristics and the peritonitis rate analyzed by standard NB regression analysis (expressed by RR) as well as ZINB regression analysis with logit link (expressed by OR)

Patients' characteristics	Standard negative binominal regression			Zero-inflated negative binominal regression[a]		
	RR	95% CI	*P* value	OR	95% CI	*P* value
Sex						
Male	1	-	-	1	-	-
Female	0.83	0.55 to 1.25	0.368	0.71	0.39 to 1.30	0.268
Age						
≤55 years	1	-	-	1	-	-
>55 years	1.07	0.67 to 1.71	0.771	1.15	0.95 to 2.09	0.658
Body mass index (BMI)	1.07	1.01 to 1.14	0.031[b]	0.93	0.85 to 1.03	0.163
Education						
Lower than elementary school	1	-	-	1	-	-
Higher than elementary school	0.76	0.49 to 1.17	0.213	1.97	1.08 to 3.59	0.029[b]
DM						
No	1	-	-	1	-	-
Yes	0.64	0.41 to 1.01	0.52	0.81	0.44 to 1.54	0.534
HD before PD						
No	1	-	-	1	-	-
Yes	0.99	0.64 to 1.54	0.985	1.43	0.81 to 2.54	0.217

Abbreviations: CI, confidence interval; DM, diabetes mellitus; HD, hemodialysis; NB, negative binomial; PD, peritoneal dialysis; RR, rate ratio; ZINB, zero-inflated negative binomial

[a] The Vuong test results were significant ($P<0.05$), recommending to report findings with the ZINB analyses.

[b] *P* value <0.05 is considered significant.

bottles without centrifuging large amount (50 mL) of the fluid, due to lack of facility (22). However, the rate of culture negative peritonitis was lower than what was previously reported to be 55% in Iran by Najafi et al, which could be explained by the different time period (it was between 1995 and 2006) and improved detection of microorganisms in subsequent years (19).

A few studies have been conducted to identify the risk factors associated with PD peritonitis (23-25). They found older age, female gender, smoking, lower educational levels, obesity, black race, and transfer from HD to PD as independent risk factors. While BMI and the rate of hypertension were significantly higher and educational level was lower in patients with peritonitis; However, in regression analysis, BMI was the only variable independently associated with higher rate of peritonitis. Few studies examined the impact of BMI on peritonitis rate, among them, there were an Australian and an Indian study which found greater risk of peritonitis in obese patients (23,24). Possible mechanisms are higher susceptibility of fat tissues to infection, and a higher rate of residual renal function loss in obese individuals (23,26).

By evaluating the impact of different factors on peritonitis-free survival, we found that lower education (lower than elementary school) was associated with earlier occurrence of PDAP. In addition, as the ZINB regression model showed, the odds of having no peritonitis increases in patients with higher education (OR=1.97). Therefore, the education level was the only variable linked to zero peritonitis rate. In our knowledge, there is only one study which explored the effect of educational level on peritonitis-free survival (25). Consistent with our study, Chern et al found that lower than elementary school level of education was associated with peritonitis-free survival and earlier occurrence of PDAP. Considering the high proportion of patients with lower educational level in our PD population, it is essential to consider these patients as high risks for PDAP and to emphasize the role of training by implementing more comprehensive training programs.

In the present study we not only evaluated the impact of factors on peritonitis rate, but also did an analysis on the peritonitis-free survival which helped us to find factors associated with earlier occurrence of peritonitis. In the best of our knowledge, our study is the first one which applied the ZINB regression model in order to find the factors associated with zero-peritonitis. More study is needed to clarify the role of this model for analyzing PDAP data.

6. Conclusions

In conclusion, BMI was a risk factor for higher peritonitis rate. Higher education level was associated with lower peritonitis-free survival and higher chance of having no peritonitis. Although the peritonitis rate was less than the ISPD recommendation, it was close to that which

necessitates the need for reviewing our protocols as well as more attention to patient training particularly in patients with higher BMI and lower educational level. Because the number of patients who have never experienced peritonitis was excessive, ZINB regression model should be considered when analyzing PDAP data.

Limitations of the study

Among the limitations of this study, we can name the possibility of incomplete records with respect to collecting some of the data from medical records of patients. In addition, we did not include biochemical parameters such as albumin in the analysis. Due to low number of patients we could not consider underlying disease such as PCKD or CGN in the analysis.

Authors' contribution

SEJ contributed to the original study design, data acquisition. FA collected and verified the field data. VE and SEJ wrote the original manuscript version. VE, SEJ and SP contributed to data analysis and rewrote the final draft. All authors have read and confirmed the final draft and agreed to its publication.

Conflict of interest

The authors declare no conflicts of interest.

Ethical considerations

Ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

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