FACTORS ASSOCIATED WITH DIALYSIS WITHDRAWAL IN DIALYSIS PATIENTS

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Abstract
Background: Research on the factors associated with dialysis withdrawal in dialysis patients has been limited. Authors have used different definitions for dialysis withdrawal, resulting in inconsistent findings. The objective of this study was to determine the factors associated with dialysis withdrawal in dialysis patients. Methods: This retrospective study extracted patient information from the electronic renal patient management systems at the Grand River Hospital. A total of 723 patients who initiated renal dialysis therapy (> 30 days of duration) in the renal dialysis program at Grand River Hospital (GRH), Ontario, during the period from 1st January 2012 to 30th September 2017 were consecutively included in the study. Logistic regression was used to determine the factors: age, sex, modality, comorbidities, the cause of primary renal disease, dialysis modality, and duration of dialysis-associated with dialysis withdrawal. Dialysis withdrawal was defined as “patient declined further treatment or voluntary withdrawal from the dialysis program”. Results: The mean age of the sample was 64.86 ± 14.89 years, and 62.8% (n = 454) were males. The prevalence of dialysis withdrawal was 9.41% (n = 68). The logistic regression model showed that factors associated with dialysis withdrawal were as follows: cardiac disease Adjusted Odds Ratio (AOR)= 1.921; 95% CI= 1.126–3.278, hypertension AOR = 5.711; 95% CI = 1.322- 24.676, dementia AOR = 3.042; 95% CI = 1.325–6.983, age AOR = 1.035; 95% CI = 1.012- 1.058 and duration of dialysis AOR = 0.999; 95% CI = 0.999–1.00. Conclusion: In this study we show that age, cardiac disease, hypertension, and dementia are significant predictors related to dialysis withdrawal. The findings might help in identifying patients who are more likely to withdraw from dialysis at the start of dialysis. Future researchers and nephrologists should design and conduct intervention studies focusing on strategies controlling the severity of comorbidities (cardiac disease and hypertension), regular assessment and monitoring of the progression of dementia, and other dialysis program changes to help patients make more informed decisions regarding dialysis withdrawal.

Introduction
Globally, the incidence of ESRD (End-Stage Renal Disease) and dialysis therapy initiation has been relatively stable, but recently the prevalence of both Chronic Kidney Disease (CKD) and dialysis has
been increasing, mainly because of long survival rates [1-3]. The highest treated ESRD incidence rate is reported in Thailand, the US and Mexico; whereas, the highest prevalence rate is found in the Taiwan, Japan and the US [4]. The incidence of ESRD in Canada is 200 (ppm [per million population]), which is higher than many advanced countries [4].

Despite the importance of dialysis in ESRD, authors have reported a wide range (8-31%) of dialysis withdrawal [5-8]. Dialysis withdrawal is one of the main causes of mortality in CKD patients [9]. Few authors have explored factors associated with dialysis withdrawal. Authors have reported an inconsistent association between factors such as age, gender, comorbidities, the cause of primary renal disease, and duration and type of dialysis modality with discontinuation of dialysis, technique failure and dialysis withdrawal [5-8,10-16].

These contradictory and inconsistent findings might be account for in several ways. Authors have defined dialysis withdrawal as withdrawal due to different reasons and causes, such as discontinuation, withholding, treatment refusal by patients and caregivers, and technique failure [10-17]. Some studies have used small sample sizes, resulting in type II error (false negative) [10,11], and some have not addressed mental health factors, such as depression/anxiety, dementia, and bipolar disorder [18] related to dialysis withdrawal. Some studies have indicated that mental health diseases have a stronger association than physical comorbidities in relation to dialysis withdrawal [13,19].

Executive summary report of Kidney Disease Improving Global Outcomes (KDIGO) [20] have highlighted that there is no universal definition of dialysis withdrawal, limiting use of available data for healthcare resource management and for research purposes. The report recommended that dialysis withdrawal should be based on: patient voluntary choice, if not having decision making capacity then based on his previous discussion through Advance Care Planning (ACP) or on legal agents’ requests or patients having irreversible neurologic impairment [20].

The objective of the study was to determine the physical and mental health predictors associated with dialysis withdrawal “patient declined further treatment or voluntary withdrawal from the dialysis program”, in renal dialysis patients. This understanding of the direction and strength of association among predictors with dialysis therapy will help to improve clinical decision making by identifying
patients who might have a higher risk of dialysis withdrawal, providing solutions, removing barriers, and facilitating the participation of patients in the decision making.

Methods

Study Design and Setting:
The study used a cross-sectional study design, retrospectively reviewing the electronic records of dialysis patients from 1st January 2012 to 30th September 2017 in a large tertiary care hospital in Ontario. The hospital provides full spectrum of Chronic Kidney Disease services, including nephrology clinics, pre-dialysis, hemodialysis, peritoneal dialysis, home hemodialysis, and pre transplantation for eligible patients living in Waterloo region and Wellington county. The hospital renal program is linked to the provincial agency (Ontario Renal Network (ORN)). The ORN plays a key role in treatment and management policies for the delivery of CKD services in Ontario.

Patients:
All patients following the selection criteria during the study period were consecutively included in the study. The study cohort included incident adult (> 18-years-old) dialysis patients with at least 30 days or more of duration of dialysis, during the study period from February 2012 to October 2017. The total duration of dialysis was measured by the first day the patient was dialyzed at home or hospital and the last date of dialysis of any modality. Patients with dialysis duration less than 30 days were not included in the study. Since the study only include incident dialysis population, patients started dialysis before February 2012 were excluded.

The Tri-Hospital Research Ethics Board (THREB) and the University Human Research Ethics Committee approved the research project (THREB File # 2016-0619) along with the waiver of “the requirement to obtain patient informed consent”.

Data Collection:
The data were extracted from Nephrocare® (electronic patient record system for renal patient management) and supplementary information related to patients as part of chart review. First, the data for the selected variables were extracted from Nephrocare® during February 2012 to October
2017. Each of the selected variables were recorded in excel by the two graduate students. Some patients were randomly selected, and their medical records were reviewed for validation and quality of data entry by the two students. The third step was to complete the missing values by reviewing and supplementary information related to patients as part of a chart review by the three graduate students. Each patient has several clinical notes and assessments summaries (reports), and the logic for identifying most relevant reports included: reports near the start of the dialysis, referral letter, nephrologists assessments, discharge reports, and anesthesiologist reports.

During the review of clinical notes, if a diagnosis was found in relevant notes, that diagnosis was recorded in the dataset. For comorbidities, if there was any report of a diagnosis by the clinician at the start of dialysis, the patient was considered as having the comorbidity, irrespective of subsequent recovery or improvement in the condition of that disease.

**Study Variables:**

The dependent variable was dialysis withdrawal, defined as “patient voluntarily refused dialysis treatment and withdrew from the dialysis program, followed by the nephrologist’s consultation and confirmation”. The independent variables were: age, gender, cause of primary renal disease, coded as diabetes, renovascular disease, nephritis, others and unknown. Comorbidity included diabetes, cardiac disease, hypertension, malignancy, depression, dementia, bipolar disorder, and vascular accident. Cardiac disease was diagnosed on the basis of the presence of any of the disease: Coronary Artery Disease (CAD), cardiac arrhythmia, cardiac failure, cardiac valvular disease, pericardial disease, cardiomyopathy, and congenital heart disease. Modality was categorized as Hemodialysis (HD) or Peritoneal dialysis (PD) at the time of 30 days of starting the dialysis. Duration of dialysis was measured from the first day of dialysis to the last day of dialysis or any terminal event, such as withdrawal, death, transplant or lost to follow up.

**Data Analysis**

All the data were analyzed using SAS® studio University Edition. The descriptive data include means, standard deviations, and frequencies and percentages. The binary logistic regression was used to assess determinants of dialysis withdrawal. For this approach, a p-value (level of significance) of 0.05
was considered significant. First simple logistic regression analysis was conducted between each predictor: age, gender, the cause of primary renal disease, diabetes, cardiac disease, hypertension, malignancy, depression, dementia, bipolar disorder and vascular accident, modality and duration of dialysis with dialysis withdrawal. All predictors with a p-value < 0.2 were included in the final logistic regression model.

Results
Baseline Characteristics of Dialysis Population
The study included 723 dialysis patients. The mean age of the sample was 64.86 ± 14.89 years, with minimum and maximum values of 19 and 94 years respectively. The majority (54.1%) of the patients were between 61 to 80 years of age, and 62.6% (n = 453) were male. The most common comorbidity was hypertension (88.8%), followed by Diabetes (63.8%). The mean duration of dialysis was 544.80 ± 486.83 days with minimum and maximum values of 30 and 2009 days. The majority (47.2%) of the patients have a duration of dialysis for less than 1 year. Table 1 provides a detailed description of the patient characteristics.

Characteristics of the Dialysis Withdrawal Group
We found that, out of 723 dialysis patients, 9.41% (n = 68) had dialysis withdrawal. The majority of the dialysis withdrawal patients were males (66.18%) with a mean age of 71.72 ± 13.90 years. Considering the majority of dialysis patients had one year or less duration of dialysis, duration of dialysis was mentioned in days rather than years to better determine the association for logistic regression model. The mean duration of dialysis within the dialysis withdrawal group was 411.88 ± 466.06 days. Table 1 provides a detailed description of the dialysis withdrawal group characteristics.

The primary causes of renal disease in dialysis withdrawal group are shown in Table 2.

Logistic Regression:
The final regression model is shown in Table 3 with model estimates and adjusted odds ratios of the predictors. The results indicated that cardiac disease [p = 0.016], hypertension [p = 0.019], dementia [p=0.008], age [p = 0.002], and duration of dialysis in days [p = 0.0092] were significantly associated with dialysis withdrawal. The adjusted odds ratio (AOR) estimates shown in Table 3 suggest that:

1. the odds of dialysis withdrawal is higher in patients with cardiac disease [AOR=
1.921; 95% CI= 1.126-3.278] in comparison to patients without cardiac disease while holding other variables held fixed;

2. the odds of dialysis withdrawal is higher in patients with hypertension [AOR = 5.711; 95% CI = 1.322-24.676] in comparison to patients without hypertension while holding other variables held fixed;

3. the odds of dialysis withdrawal is higher in patients with dementia [AOR = 3.042; 95% CI = 1.325–6.983] in comparison to patients without dementia while holding other variables held fixed;

4. one-unit increase of duration of dialysis, decreases the odds of dialysis withdrawal by a factor of 0.999 [95% CI = 0.999–1.00], while holding other variables fixed;

5. one-unit increase of age increases the odds of dialysis withdrawal by a factor of 1.035 [95% CI = 1.012–1.058] while holding other variables fixed.

Discussion

Despite the higher prevalence of dialysis withdrawal and its significant association with death in ESRD patients, the phenomenon of dialysis withdrawal remains unclear [17]. There is a gap in the literature with regards to factors associated with dialysis withdrawal, mainly because of the scarcity of available literature and inconsistent findings across various studies [17].

The results of this study show that only 9.41% (n = 68) of patients have dialysis withdrawal. This finding is supported by Chan et al. (2012) who reported a 5-year incidence rate of dialysis withdrawal as 13.4% in Australia and New Zealand [6]. However, authors have also shown higher rates of dialysis withdrawal in other studies conducted in the US (24.9%) and Japan (31%). The difference between the study findings may be attributed to religion, cultural beliefs, and ethnicity, as these factors can also influence dialysis withdrawal [5,19,21].

We found the cardiac disease [p = 0.016] and hypertension [p = 0.019] were significantly associated
with dialysis withdrawal. Comorbidities such as hypertension and cardiac disease are chronic diseases that gradually deteriorate patient health status, leading to complications that initiate a cascade of health issues [22]. These health issues increase the burden of disease and might lead patients to discontinue dialysis treatment. Similarly, Ellwood et al. (2013) and Fissell et al. (2005) found that vascular diseases and coronary artery disease were positively associated with dialysis withdrawal [7,14]; however, congestive heart failure [7,14] and other cardiovascular diseases were not associated with dialysis withdrawal [9].

The differences between the results in the present study with the previous studies [7,9,14] might be attributed to the definition of dialysis withdrawal. The present study defines dialysis withdrawal as “patient-elected withdrawal” vs. dialysis discontinuation due to any reason except recovery of kidney functions [7], unspecified dialysis termination and death [14], and all types of dialysis termination (by patient, family, physician or medical community [9]. Wetmore et al. (2017), defining dialysis withdrawal as patient elected discontinuation of dialysis (similar to our study), supported the present study findings: heart disease and hypertension increased the odds of dialysis withdrawal [18]. However, Wetmore et al. (2017) did not explore mental health components (dementia, depression and bipolar disorder) in contrast to the present study [18].

In the present study, dementia \(p = 0.008\) was found to be significantly associated with dialysis withdrawal. Irreversible neurologic impairment such as advanced irreversible dementia is one of the appropriate conditions for dialysis withdrawal [20]. Similarly, Kurella et al. (2006) [23] and Birmele et al. (2004) [9] found dementia was associated with increased risk of death and dialysis withdrawal. However, the definition of dialysis withdrawal was not clear [23], and all types of dialysis termination, including a change in modality, death, and dialysis discontinuation was used as dialysis withdrawal [9] in these studies. Patients with comorbidities have a higher risk of mental health issues than patients without comorbidities [13,24]. Similarly, patients with mental conditions, such as depressive symptoms and dementia, have a higher incidence of comorbidities [25]. Because of this complex relationship, it is difficult to distinguish and understand the biologic plausibility between the comorbid conditions and mental health issues in relation to dialysis withdrawal. This association between
comorbid conditions and quality of life with dementia might be one reason of higher odds of dialysis withdrawal in patients with dementia, as found in the present study.

The present study showed that age [AOR = 1.035; 95% CI = 1.012–1.058] was significantly associated with dialysis withdrawal; an increase in age increases the odds of dialysis withdrawal. Authors have reported that older age is associated with higher rate of dialysis withdrawal, which is similar to our findings [6,7,26]. Ellwood et al. (2013) found that increasing age was significantly associated with dialysis withdrawal [HR (Hazard Ratio) = 1.81; 95% CI = 1.75–1.88] [7]. Like the present study, Wetmore et al. (2017) define dialysis withdrawal as “patient and family elected discontinuation of dialysis” and showed higher odds of withdrawal in dialysis patients with age > 75 years [OR=1.61; 95% CI = 1.54-1.68] [18]. Older age patients have multiple comorbidities that are difficult to control, such as diabetes and hypertension that further debilitate with dialysis, leading to drastic deteriorations in physical and mental health and resulting in dialysis withdrawal [7,9,27]. Finally, the duration of dialysis in days [AOR = 0.999; 95% CI = 0.999–1.00], was significantly associated with dialysis withdrawal. Duration of dialysis might influence dialysis withdrawal, as patients with ESRD have chronic diseases and gradually deteriorate patient health status over time, which might lead to complications that initiate a cascade of health issues. These health issues increase the burden of disease and might lead patients to discontinue dialysis treatment [22,19]. Wetmore et al. (2017) have shown higher odds of withdrawal in patients with higher duration of dialysis vs. lower duration [18]. However, the odds of withdrawal in this study was close to one [AOR = 0.99; 95% CI = 0.999–1.00], and hence not clinically meaningful. This might be because most of the patients had a shorter duration of receiving dialysis treatment, as the analysis was restricted to the last 5 years, including incident dialysis patients. Patients with start of dialysis prior to the start of the study period, and those with more than 5 years of dialysis, were not captured in the study.

Limitations
The main weakness of the study is the retrospective study design, which depends entirely on the quality and completeness of patient records. The quality of the dataset for this study was also dependent on the data quality of physician notes and data entry of the electronic patient record
systems. However, a careful review of randomly selected patient records provided a limited level of assessment of the accuracy between the extracted data with source system of patient records. There was limited information about the severity of mental health diseases in our population. The only information we were able to access was presence and absence of mental health disease at the baseline (start of dialysis) and their association with dialysis withdrawal. Further comment about whether their dementia was later progressed into advanced stage or remain same (no change from baseline), when and how it was diagnosed and treated was not possible, due to study design and data limitations.

Further, this study was unable to explore the relationship between financial burden, beliefs, and cultural and personal views in relation to the decision to withdraw treatment by either family or individual. However, the objective of the study was to identify factors at the start of dialysis between the two groups to identify population at risk and early screening and intervention.

These limitations, though beyond the scope of the current study, are highly relevant for determining the factors that influence dialysis withdrawal. Being a single-center study, the generalizability of our study is also limited. However, consecutive sampling was performed to make the sample a better representation of a larger population. Due to the cross-sectional nature, of our study, we are unable to comment on the causal association between identified factors with dialysis withdrawal.

Advancement of Knowledge and Application in Practice: Implications of the Study

Our findings were based on patient voluntarily refused dialysis treatment rather than patients who died or patients who likely faced imminent death and did not truly withdraw (as withdrawal is commonly understood), as reported in many previous studies. The identified factors associated with dialysis withdrawal (voluntary withdrawal) will help understand what are the factors at the baseline (start of dialysis) that are associated with dialysis withdrawal during dialysis. The findings will likely help clinicians and researchers develop a screening instrument by including the predictors identified in the study, such as cardiac disease, hypertension, and dementia, to identify patients with a higher risk of dialysis withdrawal at the time of enrolment. Some of these predictors are highly prevalent in
the dialysis population. Intervention studies should develop models and instruments further classifying severity of these predictors and how they affect withdrawal and assigning weights based on severity of the disease. This instrument might also help clinical decision making and better engage patients in their care when the risk of dialysis withdrawal is discussed at the beginning of dialysis and throughout the entire treatment.

One of the most important findings was the identification of a mental health component for dialysis withdrawal, including dementia as one of the factors associated with dialysis withdrawal. KIDGO [20] mentioned irreversible neurologic impairment as one of the reasons for dialysis withdrawal. Renal Physicians Association has also provided many tools with acceptable psychometrics for assessment of mental health issues such as cognition, decision making capacity, depression, etc. in dialysis patients [28]. We measured mental health status (including dementia) at the start of dialysis. We assume, that patients with dementia, do not have severe or advanced stage, as advanced irreversible neurologic impairment is one of the contraindication of start of dialysis and dialysis withdrawal. The results showed dementia as a significant factor associated with dialysis withdrawal; highlighting that patients with dementia vs non dementia (at the start of dialysis) are more vulnerable to dialysis withdrawal.

Due to retrospective cross sectional nature of the study, we cannot infer whether the severity and stage of dementia progressed or remain the same for these patients and the use of mental health screening instruments and frequency of these assessments for these patients. In clinical practice, most dialysis programs screen patients for severe mental health issues prior to the enrollment of the dialysis program and potentially exclude patients with severe mental health conditions. This study identified a need for a modified mental health screening measure specific for dialysis patients, and the need for continuous monitoring of a patient’s mental health. Lack of social support and mental health services might be one of the main barriers of the continuity of dialysis. These two components are highly interrelated since lack of social support has a negative influence on mental health outcomes. However, due to the limited sample size and availability of data, we did not explore these topics in depth. To identify the mediators that influence the relationship between predictors, such as social support, mental health, quality of life, and dialysis
withdrawal, future researchers should conduct studies with larger sample sizes, and qualitative exploration of the process.

In clinical practice, most dialysis programs screen patients for severe mental health issues prior to the enrollment of the dialysis program and potentially exclude patients with severe mental health conditions. This study identified a need for a modified mental health screening measure specific for dialysis patients, and the need for continuous monitoring of a patient's mental health.

Conclusions
The study showed a low rate of dialysis withdrawal (9.41%) in a cohort (N = 723) of dialysis patients included in the study. Age, cardiac disease, hypertension, dementia, and duration of dialysis were associated with dialysis withdrawal. These findings might help in identifying a cohort of patients who are susceptible to dialysis withdrawal at the start of dialysis.

Declarations
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Competing Interests:
None of the authors have any competing interests

Availability of Data and Materials:
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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Tables
Table 1. Characteristics of Dialysis Group (all patients in the study sample) and Dialysis Withdrawal Group

| Age in years, n (%) | All patients (N= 723) | Dialysis Withdrawal (N=68) |
|---------------------|----------------------|---------------------------|
| ≤ 40                | 52 (7.2)             | 3 (4.4)                   |
| 41-60               | 179 (24.8)           | 9 (13.2)                  |
| 61-80               | 391 (54.1)           | 34 (50)                   |
| >80                 | 101 (14)             | 22 (32.4)                 |

| Gender n (%)        | All patients (N= 723) | Dialysis Withdrawal (N=68) |
|---------------------|----------------------|---------------------------|
| Males               | 453 (62.6)           | 45 (66.2)                 |
|                | Females |                |              |
|----------------|---------|----------------|--------------|
|                | 270 (37.3) | 23 (33.8)      |              |
| Comorbidities n (%) |         |                |              |
| Diabetes       | 461 (63.8) | 41 (60.3)      |              |
| Infarct        | 198 (27.4) | 23 (33.8)      |              |
| Heart Disease  | 413 (57.1) | 48 (70.6)      |              |
| Vascular accident | 196 (27.1) | 26 (38.2)      |              |
| Malignancy     | 228 (31.5) | 27 (39.7)      |              |
| Lung disease   | 172 (23.8) | 22 (32.4)      |              |
| Hypertension   | 642 (88.8) | 65 (95.6)      |              |
| Mental health  | 232 (32.1) | 25 (36.8)      |              |
| Depression     | 213 (29.5) | 19 (27.9)      |              |
| Dementia       | 40 (5.5) | 9 (13.2)      |              |
| Bipolar disorder | 18 (2.5) | 2 (2.9)      |              |
|                |         |                |              |
| Modality n (%) |         |                |              |
| HD             | 592 (81.9) | 59 (86.8)      |              |
| PD             | 131 (18.1) | 9 (13.2)      |              |
| Duration of Dialysis in years |         |                |              |
| ≤1             | 341 (47.2) | 41 (60.3)      |              |
| ≤2             | 159 (22) | 12 (22.1)      |              |
| ≤3             | 108 (14.9) | 4 (5.9)      |              |
| ≤4             | 70 (9.7) | 3 (4.4)      |              |
| >4             | 45 (6.2) | 5 (7.4)      |              |

Abbreviations: HD: hemodialysis; PD: peritoneal dialysis

Table 2. Primary Cause of Renal Disease in Dialysis Withdrawal Group (N=68)
| Category          | Summary Statistics n (%) |
|-------------------|--------------------------|
| Diabetes          | 21 (30.9)                |
| Renovascular      | 10 (14.7)                |
| Others            | 16 (23.5)                |
| Uncertain         | 14 (20.6)                |
| Nephritis         | 7 (10.3)                 |

**Table 3. Final Logistic Regression Model**

| Parameter                      | p     | AOR   | 95% CI AOR         |
|--------------------------------|-------|-------|--------------------|
| Intercept                      | <.0001|       |                    |
| Duration of dialysis in days   | 0.0092| 0.999 | 0.999 – 1.00       |
| Modality HD vs PD (Ref)        | 0.4388| 1.348 | 0.633 – 2.870      |
| Age in years                   | 0.0024| 1.035 | 1.012 – 1.058      |
| Diabetes Yes vs No (Ref)       | 0.1359| 0.660 | 0.382 – 1.140      |
| Cardiac Disease Yes vs No (Ref)| 0.0166| 1.921 | 1.126 – 3.278      |
| Hypertension Yes vs No (Ref)   | 0.0196| 5.711 | 1.322 – 24.676     |
| Dementia Yes vs No (Ref)       | 0.0087| 3.042 | 1.325 – 6.983      |

Note. *p>0.05 as significant, 95% CI AOR; 95% Confidence Interval for Adjusted Odds Ratio
Abbreviations: AOR, adjusted odds ratio; CI, confidence interval; HD, hemodialysis; PD, peritoneal
dialysis