Dialyzer Reuse with Peracetic Acid Does Not Impact Patient Mortality

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INTRODUCTION

The potential risks and benefits of dialyzer reuse have been actively debated in the medical literature since the early 1960s.

While numerous studies have demonstrated no adverse effects of reuse on clinical outcomes,[1,2] a recent publication reported a dramatic drop in mortality when centers switched to single-use dialyzers.[3]

Our objective was to determine the effect of dialyzer reprocessing with peracetic acid on patient mortality using techniques to control for potential confounding: instrumentation variable analysis and propensity-score matching.

METHODOLOGY

- Prevalent (>120 days) hemodialysis (HD) patients as of January 1, 2009 were followed for one year and days at risk were calculated. Any death that occurred within 30 days of the last treatment was included in the analysis.
- The instrumental variable analysis defined "single-use" clinics as those where 100% of dialysis sessions were conducted using single use dialyzers, n=183) and "reuse" centers as those where ≥ 95% of patients used dialyzers reprocessed with peracetic acid, n=301; Table 1).
- The propensity score-matched patient-level analysis compared the likelihood of death with single-use versus reuse across all of the LDO's clinics among prevalent in-center HD patients in 2009 (Table 2).

RESULTS

Table 1. Patient characteristics: instrumental variables analysis

	Non-reuse Clinics (0%) 10,182 pts 183 centers	Reuse Clinics (> 95%) 17,223 pts 301 centers	p-value
Age (years), mean, SD	62.8 (±14.9)	62.8 (±14.8)	NS
Vintage (years) mean, SD	4.34 (±2.73)	4.31 (±2.76)	NS
Race(%)			
African-American	51.4%	26.7%	
Caucasian	35.0%	34.1%	
Hispanic	8.2%	27.9%	
Asian/Pacific Islander	1.2%	5.5%	<0.0001
Native American	0.9%	3.0%	
Other	3.3%	2.7%	
Male (%)	56.1%	55.3%	NS
Diabetes (%)	42.7%	50.8%	<0.0001
Av fistula (%)	56.6%	58.5%	0.0025
Kt/V, mean SD	1.66 (±0.33)	1.71(±0.33)	<0.0001
Charlson index, mean, SD	5.95 (±2.25)	6.04 (±2.16)	0.0009

Table 2. Patient characteristics: propensity score-matched sample

	Single-use 13,801	Reuse 13,801	p-value
Age (years), mean, SD	61.7 (±14.8)	61.6 (±15.3)	NS
Vintage (years) mean, SD	4.36 (±2.73)	4.32 (±2.74)	NS
Race(%)			
African-American	52.2%	37.7%	
Caucasian	32.9%	36.3%	
Hispanic	8.8%	17.7%	
Asian/Pacific Islander	2.3%	4.0%	<0.0001
Native American	0.6%	1.5%	
Other	3.2%	2.8%	
Male (%)	55.8%	56.7%	NS
Diabetes (%)	40.1%	39.6%	NS
Av fistula (%)	55.3%	55.6%	NS
Kt/V, mean SD	1.66 (±0.34)	1.66(±0.32)	NS
Charlson index, mean, SD	5.80 (±2.24)	5.77 (±5.74)	NS

Table 3. Unadjusted and adjusted mortality by single-use and reuse centers

	Non-reuse Clinics	Reuse Clinics
Deaths	1357	2362
Mortality (%)	13.33%	13.71%
Deaths/100 Pt-years(95% CI)	15.9 (15.0,16.7)	16.2 (15.5,16.8)
Crude HR (95% RL)	Ref	1.02 (0.95,1.09)
Adjusted* HR (95%RL)	Ref	1.04 (0.97, 1.12)

* adjusted for race and percentage of patients with diabetes as cause of ESRD

Table 4. Mortality: propensity-score-matched sample

	Single-use 13,801	Reuse 13,801
Deaths	1785	1789
Mortality (%)	12.93%	12.96%
Deaths/100 Pt-years (95% CI)	15.5 (14.8,16.2)	15.2 (14.5,15.9)
Crude RR (95% RL)	Ref	1.00 (0.94,1.08)
Adjusted RR* (95%RL)	Ref	1.04 (0.91,1.05)
Adjusted RR† (95%RL)	Ref	1.00 (0.93,1.07)

* adjusted for race

† adjusted for race, age, vintage, and the interaction of these factors

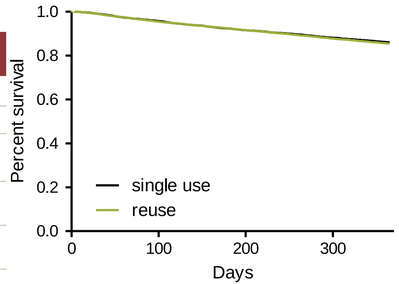

Figure 1. Survival by reuse vs. single use, propensity-score matched cohorts adjusted for race and cause of ESRD

SUMMARY OF RESULTS

- In the instrumental variable analysis, the unadjusted death rate per 100 patient-years was not meaningfully different between high reuse centers and single use centers (16.2 versus 15.9; Table 3).
- The adjusted hazard ratio was also not statistically significant for patients at clinics with high reuse compared to those at centers with no reuse.
- In the propensity-score matched analysis, patients with reuse did not have a significantly lower death rate per 100 patient-years than those without reuse (15.2 versus 15.5; Table 4).
- Adjusted survival curves reflect this lack of meaningful difference between the cohorts (Figure 1).
- Despite statistical adjustment, residual confounding by indication may remain in any retrospective analysis.

KEY LEARNINGS

- ✓ Center-level and patient-level analyses showed no association between dialyzer reuse and mortality over the course of 1 year.
- ✓ These data support the larger historical body of literature, in which studies that adequately address confounding show reuse had no adverse effect on clinical outcomes.

[1] Fan, Q, et al. *Am J Kidney Dis.* 2005;46:661-668.
[2] Port, FK, et al. *Am J Kidney Dis.* 2001;37:276-286.
[3] Lacson, E, et al. *Clin J Am Soc Nephrol.* 2011;Feb.6(2):297-302.

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