



Fatal Dialysis Vascular Access Hemorrhage

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Bleeding from dialysis vascular access (arteriovenous fistulas, arteriovenous grafts, and vascular catheters) is uncommon. Death from these bleeds is rare and likely to be under-reported, with incident rates of fewer than 1 episode for every 1,000 patient-years on dialysis, meaning that dialysis units may experience this catastrophic event only once a decade. There is an opportunity to learn from (and therefore prevent) these bleeding deaths. We reviewed all reported episodes of death due to vascular access bleeding in Australia and New Zealand over a 14-year period together with individual dialysis units' root cause analyses on each event. In this perspective, we provide a clinically useful summary of the evidence and knowledge gained from these rare events. Our conclusion is that death due to dialysis vascular access hemorrhage is an uncommon, catastrophic, but potentially preventable event if the right policies and procedures are put in place.

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Introduction

Approximately 2.6 million people now receive renal replacement therapy, the majority being treated with hemodialysis (HD).¹ HD requires access to the blood circulation via a central vascular catheter (CVC), an autologous arteriovenous (AV) fistula (AVF), or a synthetic AV graft (AVG), collectively referred to in this article as vascular access. The frequent use of such vascular access (up to 6 times per week) repeatedly exposes the patient to risk for

hemorrhage from a variety of causes. The aim of this perspective is to review what is known about fatal hemorrhage related to HD vascular access, including the current epidemiology, risk factors, and preventive practices. We provide clinical insights from reported deaths due to vascular access bleeding in Australia and New Zealand (ANZ) over a 14-year period, together with individual dialysis units' root cause analyses.

Epidemiology of Fatal Vascular Access Hemorrhage

Fatalities due to vascular access hemorrhage in the reported literature are rare. Ellingson et al,² examining data from the United States in 2000 to 2007, found that 0.4% of dialysis deaths (n = 88) attributed to fatal vascular access hemorrhage (FVAH), and Suri et al,³ 0.8% (n = 2) in the assessment of data from the Frequent Hemodialysis Network (FHN) Daily Trial. Gill et al⁴ reported 100 deaths due to FVAH between 2003 and 2011 in the United States, whereas Mazzoleni et al⁵ reported 2 FVAH deaths in Belgium between 2005 and 2012. The US Veterans Health Administration Center for Patient Safety analyzed 47 episodes of bleeding during dialysis between 2002 and 2008, of which "some of these resulted in fatalities."^{6(p1)}

Using a systematic search strategy of the National Coronial Information System (containing coroner's reports from all Australian states and New Zealand, www.ncis.org.au), the ANZ Dialysis and Transplant Registry (ANZDATA, www.anzdata.org.au), published cases from ANZ, State Renal Network reports,

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and individual renal units, we identified all ANZ cases for which cause of death was reported as death due to dialysis access hemorrhage during the 14 years from 2000 to 2013 (Fig S1, available as online supplementary material). After removal of duplicates and alternate causes of death, we identified 79 people as having died from FVAH. During the period of observation, the annual number of deaths ranged from 2 to 10 in any given year (Fig S2). As also observed by others, we found incidence to be low. For example, in 2013, there were 9,468 people on HD therapy in Australia and 1,752 in New Zealand,⁷ and of the 1,508 deaths in ANZ dialysis patients that year, 9 were attributable to FVAH, therefore contributing to 0.6% of HD deaths overall, or approximately 1 death for every 1,250 patient-years of HD.

Such a low incidence of FVAH means that most dialysis units are likely to ever encounter only 1 fatal event. This tenet is supported by observations of Ellingson et al,² who described 88 confirmed cases over a 90-month period from 58 US dialysis facilities, with a maximum of 3 in any 1 unit. On the other hand, Mazzoleni et al⁵ reported all cases of hemorrhage, fatal or not, and determined a higher rate of 0.045 hemorrhage/1,000 patient-days, suggesting that near-miss events are substantially more common.

Pathophysiology of Vascular Access Hemorrhage

Based on previous reports in the literature,^{2,4,5,8} 3 broad groups of causal factors for FVAH may operate independently or in combination. First, specific complications associated with the vascular access, such as aneurysmal formation and/or bacterial infection, lead to weakening of the vessel wall, increasing the subsequent risk for bleeding. Second, patient-related factors, including multiple comorbid conditions and medications, may contribute to increased bleeding risk, including reduced cognitive function and the ability to self-manage an initial bleed. Third, dialysis procedure-related factors, specifically disconnection at the patient-machine interface (including detection of needle dislodgement or catheter misconnection), may lead to an FVAH.

Risk Factors for FVAH

Due to the rarity of FVAH, assessing independent risk factors is difficult. However, several potential risk factors can be ascertained. The type of vascular access in use appears to be an important risk factor for FVAH. In the ANZ cohort we analyzed, 20% and 22% of FVAH events occurred in AVGs and CVCs, respectively (Table S1), markedly higher than their overall use in ANZ during this period (prevalent use in ANZ at December 31, 2013, was 7% for AVGs and 14% for CVCs).⁷ Similarly, Ellingson et al² identified AVGs as a risk factor, with cases of FVAH having a

6-fold greater likelihood of using an AVG compared with 38 control patients (controls were randomly selected from the same dialysis facility, but had died of non-vascular access hemorrhage causes). Synthetic AVGs are more prone to pseudoaneurysm formation than AVFs due to their higher intra-access pressure and lack of venous tissue at the puncture site, meaning that repair mechanisms are limited to clot and fibrous tissue.⁹ Pseudoaneurysm formation increases the likelihood of spontaneous rupture of the vessel.¹⁰

CVCs were also a risk factor for FVAH in our data, contributing to 17 (22%) deaths for which site of bleeding was recorded. Of the 17 fatal CVC bleeds, 10 related to insertion or removal procedures and 4 were disconnections during a dialysis session (Table 1). In the literature, exsanguination from disconnection of CVCs is mostly reported in case series¹¹⁻¹³ and is not as well studied as needle dislodgement from AV access.⁶ The US Veterans Affairs National Center for Patient Safety reported that 20% of all (fatal and nonfatal) bleeding episodes were attributable to CVCs (often in the intensive care unit or dialysis isolation rooms),^{6,14} similar to the 21% for FVAH found by Ellingson et al.² In reported cases of bleeding from CVCs, the most common reasons included failure to cap catheter ports, loose connections with the dialysis machine circuit, and inadvertent removal.¹⁵⁻¹⁸ Although catastrophic, it should be realized that exsanguination from CVCs is an infrequent complication. In absolute terms, other

Table 1. Recorded Cause of Death

Cause of Death	n/N (%)
Bleeding arteriovenous access	
AVF	48/79 (61)
AVG	11/79 (14)
Catheter insertion or removal bleed	10/79 (13)
Catheter disconnection bleed	4/79 (5)
Postoperative AVF bleed	2/79 (3)
Bleeding catheter not otherwise specified	2/79 (3)
Suicide; cut catheter	1/79 (1)
Misconnection of dialysis tubing (AVF)	1/79 (1)

Note: Data obtained from the analysis of 79 deaths in Australia and New Zealand between 2000 and 2013. Cause of death was identified by coronial reports on the NCIS, local unit root cause analyses, and as reported to ANZDATA. At the time of writing, 5 coronial cases were not concluded, 4 of which were reported to ANZDATA as "AVF bleeds." Ethical approval for this study was obtained from the Human Research Ethics Committee (Tasmania) Network (approval H0013985), the Victorian Department of Justice Human Research Ethics Committee (CF/14/15524), and the Coronial Ethics Committee of Western Australia (EC06/14).

Abbreviations: ANZDATA, Australia and New Zealand Dialysis and Transplant Registry; AVF, arteriovenous fistula; AVG, arteriovenous graft; NCIS, National Coronial Information System.

complications with CVCs, most notably catheter-related bloodstream infection, can be up to 100 times more frequent in HD populations (5.1 episodes/1,000 catheter-days¹⁹ compared to 0.045 episode/1,000 patient-days for bleeding complications⁵).

The physical location of the vascular access may also be important; 6% of all deaths in our series were from a thigh vascular access (Table 2), which was similar to the 8% reported by Gill et al.⁴ This is likely over-represented as a contributor to fatal bleeds due to the large vessel size and consequent higher blood flow and intra-access pressure making it more difficult to control bleeding.

Infection of the AV access is an important risk factor due to interference of the usual repair mechanisms leading to weakness in the vessel wall, potential for subsequent aneurysm or pseudoaneurysm formation, and risk for eventual rupture. Recent infection or problems with skin integrity were reported for 16 of 31 AVF or AVG bleeds (52%) in our cohort, including 3 of the 10 who had recent surgical correction (Table 2). Infection was also the most common vascular access complication seen in the 6 months before fatal hemorrhage in the study from Ellingson et al² and was identified in 5 of the 6 AVF bleeds (83%) reported by Mazzoleni et al.⁵ Button-hole cannulation techniques^{13,20,21} have been clearly shown to increase the risk for vascular access infection and therefore may also be a potential risk factor for hemorrhage, but to our knowledge, reporting of cannulation method is not in any published reports of FVAH to date.

Finally, where the person is when the bleed occurs may be an important risk factor for hemorrhage itself, but also may influence the subsequent risk for death directly related to that hemorrhage (due to lack of readily available expertise to manage the bleeding). Reports of FVAH in facility-based dialysis patients in the United States found that the majority (78%) of bleeding episodes occurred while patients were in the community (home or nursing home), with only 12% occurring during a dialysis session. Gill et al⁴ also

reported on facility-based dialysis patients, showing that 81% of bleeds occurred while the patient was in the community, away from the dialysis unit. Data from our ANZ cohort demonstrates a similar finding, with most FVAHs occurring in the home or community setting (78%), and the rest occurring in the satellite dialysis unit (5%) or hospital setting (17%; Table S1). However, ANZ data are limited because in 49% of cases, location was not recorded.

For people dialyzing in the home (who have extensive training in self-management and often a dialysis partner present), Pauly et al reported the relative risk for death from vascular access bleed or infection in home to be 0.27 (95% confidence interval, 0.20-0.37) versus facility HD patients, consistent with the observation that serious safety events on home dialysis are rare.²² Of 79 deaths in our ANZ cohort, 12 patients were treated with home-based HD at the time of death, of whom 9 died from a bleeding AVF/AVG (place of death was not recorded in 6), 1 from CVC disconnection while receiving home dialysis, 1 from CVC insertion (in hospital), and 1 from misconnection of dialysis tubing (previously published²³).

Prevention of FVAH

Most literature on the prevention of FVAH is focused on the prevention of bleeding while receiving dialysis, which generally occurs from venous needle dislodgement or catheter misconnection. It is now well established that arterial and venous pressure alarms on dialysis machines are not sensitive enough to detect partial dislodgment^{14,24,25} and that rapid blood loss leads to hemorrhagic shock within only 1 to 2 minutes at usual blood flow rates. Many recommendations have been made in the literature to counter such events, such as proper taping of needles, tightening of connections, or the use of Luer lock devices, loose looping of blood tubing, blood leakage sensors, and heightened surveillance for confused patients.^{6,14,26-28} However, as stated, both ANZ and US data confirm that the vast majority of fatal bleeds

Table 2. Identified Issues That May Have Contributed to Death

Identified Issue	Source of Data	Total No. of Cases in Data Sources	No. Where Data Recorded	Issue Present
Recent access infection or problems with skin integrity (within 4 wk) of AVF/AVG	NCIS, unit RCA	49	31	16/31 (52%)
AVF/AVG declotted in previous 12 mo	ANZDATA	66	53	6/53 (13%)
AVF/AVG revised in previous 12 mo	ANZDATA	66	53	11/53 (21%)
Use of a thigh AVF/AVG	NCIS, unit RCA	49	14	5/14 (36%)
Coronary open cases (not yet finalized)	NCIS	48	48	5/48 (10%)

Note: Data obtained from the analysis of 79 deaths in Australia and New Zealand between 2000 and 2014. Issues were identified by coronial reports on the NCIS, unit RCA, and access interventions as reported to the ANZDATA.

Abbreviations: ANZDATA, Australia and New Zealand Dialysis and Transplant Registry; AVF, arteriovenous fistula; AVG, arteriovenous graft; NCIS, National Coronial Information System; unit RCA, unit root cause analyses.

occur from spontaneous access rupture away from the dialysis facility (most often at home, assisted living, or a nursing home), and it is therefore likely that the family and caregivers are confronting these large bleeds,²⁹ rather than dialysis unit staff.

The sharing of individual unit or network mortality review findings has allowed us to collate and share their recommendations (Box 1). We have categorized these into vascular access-, patient-, procedure-, and facility-related recommendations. Of these, the largest and most challenging areas for improvement are facility-related (clinical governance) and

patient-related (education) areas, because often the field's previous focus has been on vascular access and the dialysis procedure.

It is essential that AV access be examined physically on a frequent and routine basis: wet scabbing, frank infection, or pseudoaneurysm should trigger urgent review and intervention. However, there are only a few dialysis facilities in ANZ that systematically collect and report loss of skin integrity overlying the puncture site for routine adverse-event reporting.³⁰ There is a need for standardized monitoring and reporting of AV puncture site integrity, in a

Box 1. Summary of Recommendations and Local Practice Change From Coronial Inquiries, Journal Publications, Renal Network, and Local Unit Reviews in Australia and New Zealand

Vascular Access–Related Recommendations

Fistula/graft

- Clinical examination of AVF/AVG should occur each dialysis episode
- Vascular access site must remain visible throughout dialysis
- Documentation that cannulation site of AVF/AVG was rotated should be recorded with consideration of a cannulation plan
- Suspicion of infection should be immediately communicated to the vascular access coordinator or medical officer
- Access infection should be treated and monitored until resolution
- Confirmed bloodstream infections require a minimum duration of antibiotic treatment

Dialysis catheters

- Catheter connections should be checked and documented by 2 nurses
- Catheter connections should be checked hourly during dialysis and documented
- Catheters and their connections should be visible above clothing/blankets throughout the dialysis procedure

Patient-Related Recommendations

Patient considerations

- Medical staff should regularly review patient comorbid conditions, including medications and consider potential impact on bleeding risk
- Dialysis anticoagulation prescriptions should be regularly reviewed by medical staff

Education

- Education of both patients and staff is critical, with preference for a structured education program and provision of resources to patient
- As a minimum, all should be educated on the need to rotate cannulation site, the risk for bleeding, and immediate first aid
- Education resources have been developed by the NSW Agency for Clinical Innovation, including an information sheet, management algorithm, and “*Heed the Herald Bleed*” poster (<http://www.aci.health.nsw.gov.au/networks/renal/resources>)

Dialysis-Related Recommendations

Equipment modifications

- Consider use of a wetness detector for catheters or frail patients
- Isolation rooms should have real-time visual monitoring by staff
- Dialysis machine modifications should include the ability to detect blood leak during dialysis
- Catheter connection modifications to prevent dialysis tubing from being misconnected or disconnected

Facility-Related Recommendations

Clinical governance

- Renal units should have a management algorithm for identification, reporting, and management of altered skin integrity or bleeding associated with dialysis vascular access
- A single point of care, such as a Vascular Access Nurse Coordinator, should be considered
- Renal units should have a clear clinical communication, escalation, and handover process
- The access coordinator should maintain documentation of AVF/AVG problems, clinical review, and escalation to medical staff
- Renal units should have a standard protocol for antiseptic preparation that includes alternative options for management of skin sensitivities
- Renal units should have a standard effective taping method of dialysis cannulas
- All vascular access hemorrhage deaths should undergo unit review and results disseminated across state/national health network and be considered for publication if considered a safety issue
- All critical safety events should be reported to the relevant authority

Abbreviations: AVF, arteriovenous fistula; AVG, arteriovenous graft; NSW, New South Wales.

manner that is analogous to the reporting of exit-site infections in peritoneal dialysis programs. This need is most acute in high-risk patients such as those exposed to buttonhole cannulation or with immunosuppressive diseases or those who have undergone recent intervention to the access.

Appropriate education should be guided by the observation that fatal bleeding almost always occurs away from the dialysis facility. It is critical that patients and their caregivers are taught how to respond appropriately to episodes of bleeding that occur in the interdialytic period. A structured teaching program should be implemented, with content based around current recommendations in the literature^{8,27}: direct continuous pressure for 15 to 20 minutes until emergency medical help arrives, avoiding the application of tourniquets, blood pressure cuffs, or bandages to the extremity. The largest state in Australia (by both general and dialysis populations) has taken the lead on this issue, developing educational resources about AV access bleeding for both patients and staff and implemented at a state-wide level (Box 1). These efforts represent a start in this area, with concepts and deliverables that should be expanded through policy initiatives at a national level and enhanced for high-risk subgroups. For instance, recipients of HD are now commonly in the 8th and 9th decade with multiple comorbid conditions, including cognitive decline. The ability of patients to learn self-management of bleeding episodes may be limited, and a different coaching approach and clinical algorithm may be necessary.

Clinical governance requires effective clinical practice and policy from the individual patient to the national level, with the latter being even more important for these rare (but preventable) events. It is important to realize that education is only one component of what should be a whole system approach for the prevention of FVAH. This approach should be guided by systematic quality assurance principles. Critical preventative measures include achieving puncture site integrity at the end of each HD treatment (allowing the patient to leave the dialysis unit safely) and regular access monitoring in the dialysis facility to detect wet scabbing, infection, or pseudoaneurysm. Critical mitigation measures include the patient education described. All the activities should be nested in a heightened clinical culture of quality assurance around FVAH to drive appropriate detection and management. This should be reflected in facilities having clear and well-socialized clinical pathways designed to trigger preventative actions to avert FVAH and appropriate operating mechanisms for managing near misses and each patient who is detected to have an at-risk access.

The ability to demonstrate effective quality improvement at a single-unit level for such uncommon events is difficult, and reporting at a network, state, or federal level is necessary.

A major limitation of the current literature is the lack of sufficient detail of the event leading to and surrounding each episode of FVAH. For instance, in our study, we lacked access to data that may have been informative, such as the access cannulation technique (eg, use of buttonhole cannulation), type and amount of anticoagulation used for the dialysis episode before death, use of antiplatelet agents, and specific details on the vascular access in the days leading up to death relating to the type of local infections, venous pressures, recent effectiveness of dialysis, and physical location of the vascular access (leg or arm). Low-molecular-weight heparins, now widely used in HD in some countries, are renally cleared and may have a prolonged and cumulative effect in end-stage kidney disease, beyond the time required for actual dialysis, putting the patient at risk in the postdialysis period.³¹ Finally, the current literature includes only FVAH, rather than near misses: these latter cases are critical learning tools for dialysis providers for maintaining patient safety.²² There are important learning opportunities, based on rigorous collection, analysis, and sharing of data on all major bleeding episodes in people treated with HD, that must occur to better understand and prevent future FVAH.

Conclusions and Area for Future Research

In conclusion, deaths occur every year due to FVAH, an uncommon but preventable complication of dialysis. There is a need for more specific data for all bleeding events, not just the fatal ones, to better understand this sentinel event. Appropriate preventative measures include implementation of robust quality assurance processes and reporting around the AV puncture site integrity, accompanied by clear clinical pathways to trigger review and intervention. This should be coupled with the development of health literacy-appropriate and culturally sensitive education materials to help patients detect and self-manage VA bleeding episodes outside the dialysis facility.

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SUPPLEMENTARY MATERIAL

Table S1: Demographics at the time of death.

Figure S1: Flow chart for systematic search.

Figure S2: Histogram of ANZ cases with dialysis access hemorrhage as cause of death, 2000-2013.

Note: The supplementary material accompanying this article (<http://dx.doi.org/10.1053/j.ajkd.2017.05.014>) is available at www.ajkd.org

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