# Did stopping ultrasound surveillance during COVID-19 result in an increase of the dialysis access thrombosis rate?

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# Allsopp, K. Smith, L. ABSTRACT

**Purpose:** The COVID-19 pandemic resulted in cessation and subsequent reduction of routine care including the outpatient ultrasound surveillance of AVF. This unplanned service disruption allowed evaluation of effectiveness of US surveillance in reducing AVF/AVG thrombosis.

**Methods**: This study was a secondary data analysis of monthly access patency for all in-centre patients receiving haemodialysis using an AVF or AVG over a two-year period (April 2019- March 2021). The study included 298 patients with age, access type, patency and COVID status measured as variables. Thrombosis rates for the 12 months prior to COVID-19 and then during the first 12 months of the pandemic were also measured. Statistical analysis to assess mean and standard deviation for relevant variables was used. A *p*-value of <0.05 was deemed significant.

**Results**: At the end of the study an increase in thrombosis rate (%) in the nonsurveillance year was observed. (1.20) thrombosis/patient/year in the surveillance group vs (1.68) thrombosis/patient/year in the non-surveillance group). Monthly mean of thrombosed access during surveillance (M= 3.58, 95%Cl 2.19-4.98, SD = 2.193) and non-surveillance (M=4.92, 95% Cl, 3.52-6.31, SD=2.19); t (7148) =2.051, p = 0.038.

**Conclusion**: Reduction in routine Ultrasound surveillance following the COVID-19 pandemic was associated with a significant increase in access thrombosis rate. Further research is needed to unpick whether the associations seen were directly due to service changes, associated with COVID-19 or other factors during the pandemic. This association was independent of SARS-CoV-2 infection status. Clinical teams should consider alternative service delivery options including outreach, bedside surveillance to balance risks of access thrombosis versus reducing the risk of nosocomial infection with hospital visits.

**Keywords**: Access, Arteriovenous Fistula, Burden, COVID-19, Surveillance, Thrombosis, Ultrasound

#### Introduction

There can be some agreement among health care professionals that the COVID-19 pandemic has a lot to answer for, perhaps it can answer the ever elusive question as to whether ultrasound surveillance can help maintain access patency. The native arteriovenous fistula (AVF) and the arteriovenous graft (AVG) are considered the best types of access for patients with End stage renal failure to receive haemodialysis.<sup>1</sup> It has been suggested that the impact of COVID-19 on dialysis access is not yet known but it is predicted that the rates of definitive access have been severely affected. The COVID-19 pandemic has resulted in major disruption in the delivery of clinical services on a scale previously unseen<sup>.2</sup> Many patients expressed a high level of anxiety regarding attending hospital appointments during this time whilst others felt safe to attend for dialysis and appreciated leaving their home.<sup>3</sup> Changes to service delivery were inevitable, as attempts were made to reduce face-to-face consultations across both primary and secondary care, introducing telephone consultations and thus minimising patient visits to hospital.<sup>3,4</sup> The downside of telephone health visits has since been documented suggesting that even the ongoing access monitoring of patients not even on dialysis is important to prevent complications such as the mega fistula.<sup>4</sup> Current literature suggests there are many factors directly influencing dialysis access patency with vessel narrowing (stenosis) being one of them.<sup>5</sup> There are also different screening methods used to detect a haemodynamically significant AV stenosis and this study will focus on ultrasound surveillance detecting the stenosis and preventing thrombosis of the access.6,7

The outpatient ultrasound surveillance for this trust is depicted in figure 1. This service is managed by 3 renal access nurses and covers a catchment area and cohort of >450 patients. Both routine and unscheduled care is provided, and the unscheduled care can be either self-referral, nephrologist referral or dialysis unit staff. The surveillance service at this trust was stopped for 12 months whilst the renal access nurses were re-deployed to the acute COVID-19 dialysis ward, thus presenting an opportune moment to provide data for a retrospective service evaluation.

Routine surveillance of asymptomatic AVF/AVG's is controversial with conflicting studies on its benefits.<sup>8</sup> Thrombosis causing AVF failure is usually proceeded by the

development of an underlying stenosis.<sup>9</sup> Evidence supports that the surveillance and monitoring findings help the radiological interventionists surmise where the site of stenosis might be and which stenosis are clinically relevant prior to angioplasty.<sup>9</sup> During the 12 month period pre-COVID-19, 1,167 surveillance scans were performed at this trust with 365 proceeding to Plain Old Balloon Angioplasty. This represents a 1:3 ratio of Fistulogram to Scan with 33.1% of all access scans performed requiring radiological intervention to help maintain patency. Even though research into ultrasound surveillance and access patency has been dominated by the RCT, a systematic review of the Cochrane renal group trials discovered that there had been no RCT's of duplex ultrasound screening of AVF's answering the hypothesis of 'there is no evidence to refute or support Doppler ultrasound screening'.<sup>10,11</sup>

Clinical practice guidelines on vascular access for haemodialysis suggest that 80% of long term dialysis patients should receive dialysis treatment via a definitive access either AVF or AVG.<sup>12</sup> Further guidelines recommend that all patients on long term haemodialysis should have their access monitored and maintained to minimise failure but this is not defined to a set standard leaving clinical governance meetings to create their own.<sup>12</sup> Dialysis patients experience a higher burden of treatment and lower health related quality of life compared to pre-dialysis patients.<sup>13</sup> It has been suggested that treatment burden should be considered in Chronic kidney disease management and factors that increase it should be considered when designing healthcare interventions directed at CKD patients.<sup>13</sup> The pandemic could be viewed as a catalyst for change for vascular access programmes, little information is available about the cost of access surveillance programmes, the patient's perspectives or their quality of life raising the concern of a failing interest in access in general.<sup>1,6</sup> The aim of this study was to evaluate and measure the impact of the outpatient service being stopped so that an appropriate level of surveillance can be implemented without impacting on the patients' quality of life or jeopardising access patency. The monthly event rate of AVF/AVG thrombosis and the number of AVF's/AVG's being used each month over the 24month period will hopefully present the appropriate data to help set a standard.

		ind Service for Renal Access Patients		
Stream 1: Structured Surveillance		Stream 2 : Clinician Lead Surveillance	Stream 3: Open Access Referra	
New AVF/AVG	Post Intervention	Complex AVF/ AVG Access	Routine	Urgent
2 week SD Clinic	Early Routine	If at any point a patients dialysis access becomes <b>complex</b> and can no	< 6 Wk scan	< 2 Wk scan
6 week US Scan 2-6 Wk 3 month US Scan 6 month US Scan 9 month US Scan 12 month US Scan		longer be managed in structured surveillance format, it is the discretion of the specialist team to request surveillance as and when deemed necessary based on their expert clinical judgement. Note: Request states 'Clinician Lead Surveillance' with specific question to	Based on clinical indication/ complication. Referral raised at any time by the clinical team.	
No complications = ongoing 12 month clinical review + US Scan Note: If functioning well, it is the discretion of the referring clinician to skip 6 and/or 9 month interval.		guide Vascular Scientist to produce a tailored report.		V 1.0, 5/03/21 Author: Lila Wright Review Date: 4/6/3

Figure 1: Outpatient ultrasound surveillance service for dialysis access.

# Methods:

This is study is a service evaluation using secondary data from the hospital data base Renal Proton (Clinical computing, UK) and the Clinical radiology information system (CRIS). Source data was collected from these hospital clinical core IT systems that are used in routine patient care. All 6 in-centre hospital satellite units covering a wide catchment area and involved in providing haemodialysis for the Trust were included. The framework 'PICOT' was used to formulate the study question and a ROBINS-I tool helped to formulate and thus alleviate a list of potential confounding bias.

AVF/AVGs are routinely needled by trained dialysis staff in all units. All satellite units would be using both clinical examination and ultrasound surveillance from April 2019-March 2020 to assess access patency and clinical examination only from April 2020- March 2021. The method of quasi-experimental design has been chosen to evaluate the effectiveness of surveillance and is deemed an appropriate methodology as random assignment has not been possible in this setting.<sup>14</sup>

However, quasi experimental research does not eliminate confounding variables such COVID-19 and claims have been made regarding its pro-thrombotic tendencies, particularly those severely affected but data on fistula loss secondary to infection is not yet clear. The issue that Covid-19 is associated with a hypercoagulable state and thus an increased risk of access thrombosis has been raised.<sup>15</sup>This confounding issue can be eliminated by checking the Covid-19 status on renal proton at time of access thrombosis. It has been discussed that severe COVID-19 has been associated with an increased risk of arterial and venous thrombus.<sup>16</sup> Data collected during the no surveillance period presented only one thrombosed access during a severe case of COVID-19.

Data of the monthly access patency for all in-centre patients receiving haemodialysis on either an AVF/AVG was retrospectively collected from the two-year period. The number of thrombosed access was calculated from both CRIS and PROTON for the time series of surveillance and for the time series of nonsurveillance. Each month over a 2year period, an average of 298 patients' age, access type, patency and COVID status were measured as variables. Thrombosis rates for the 12 months prior to COVID-19 and then during the first 12 months of the pandemic were analysed and reported as a percentage rate (Table 1). Statistical analysis was performed using IBM SPSS statistics version 22.0 to assess both mean and standard deviation. A *p*-value of <0.05 was deemed significant and presenting the confidence interval of 95% will help to interpret the results.<sup>17</sup>

## Inclusion criteria:

Any in centre patient having haemodialysis with an AVF/AVG on the last day of each month.

#### **Exclusion criteria:**

Transplant patient with AVF/AVG, Pre-dialysis patient with AVF/AVG, Home-dialysis patient with AVG/AVG.

#### Statistical analysis:

Both descriptive and inferential statistics were used to give different insights into the data as using both of them presents a more powerful tool for description and prediction.<sup>18</sup> Descriptive statistics will express the quantitative variables as a mean and the standard deviation which expresses the average distance from the mean. This will begin to answer the hypothesis by identifying trends and then inferential statistics in the form of an independent t-test shall determine whether equal variances can be assumed and if the *p*-value = <0.05 equal variances will not be assumed and the two sided *p*-value deemed significant. The statistical analysis was performed using SPSS version 22.0 (SPSS IBM), due to the categorical nature of the data and the fact that it was not continuous, non-parametric assumptions were assumed and the t-test performed.

#### **Results:**

A total of 481 patients, of which 202 females (33.8%) were involved in this study over the 2-year period as patients either had transplants, withdrew from treatment or changed modality. The patients were aged between 21-91 years, with a mean age of 72.05 years and a standard deviation of +/- 15.13 years. 202. The median number of patients receiving dialysis on either an AVF or AVG at the end of each month was 298, an average annual total of 3,583. Table 2 describes the patient characteristics for the 12 months pre-COVID-19 and the 12months during the pandemic and includes average number of AVF versus AVG.

Patient characteristics	April 2019- March 2020 (surveillance)	April 2020- March 2021 (no surveillance)
Total annual patients. n	3656	3511
Age (years)	72.7 +/- 15.34	71.9 +/- 14.92
Average monthly number of patients	304	292
Female, <i>n</i> (%)	106 (34.8)	96 (32.8)
Average monthly AVF's, <i>n</i> (%)	265.3 (86.6)	251.2 (85.8)
Average monthly AVG's, <i>n</i> (%)	38.7 (13.4)	40.8 (14.2)
COVID-19 cases, <i>n</i> (%)	0.0 (0.0)	36.0 (0.9)
Annual total clotted AVF&AVG <i>n (%)</i>	44 (1.2%)	59 (1.68%)

Table 2: Patient characteristics

A two sample t-test was performed to compare the thrombosis rate for the two groups (surveillance) and (no surveillance). Equal variances were not assumed as Levene's test for equality of variances produced a *p* value of <0.001. The annual rate of thrombosed access was calculated at 1.20% during surveillance and 1.68% during the period of non-surveillance. Figure 3 presents the independent t-test used to compare the two samples by looking at 'clotted' against the variable of surveillance/no surveillance.

There was a significant difference in monthly thrombosis rate between surveillance (M= 3.58, 95%Cl 2.19-4.98, SD = 2.193) and non-surveillance (M=4.92, 95% Cl, 3.52-6.31, SD=2.19); t (7148) =2.051, p = 0.038. So we can conclude that there is a statistical significance difference between the two samples.

Figure 2 presents these results as an interrupted time series graph. The monthly total of AVF/AVG thrombosed and the number of COVID-19 cases are plotted. It would appear that despite only one positive case of COVID-19 coinciding with access thrombosis in April 2020, there is a correlation between thrombosis and positive cases in months November 2020 and January 2021.

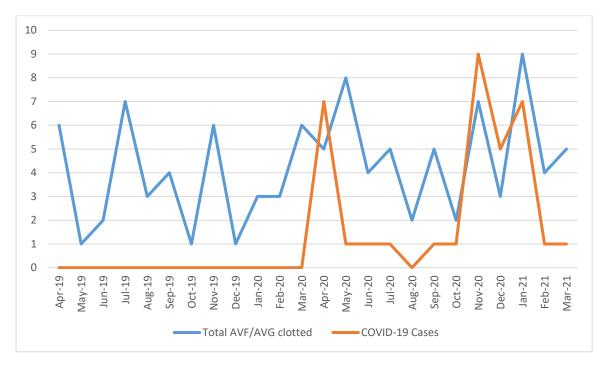


Figure 2: An Interrupted time series design showing an increase in clotting and COVID-19 at time of intervention (with-drawl of surveillance) from April 2020-March 2021

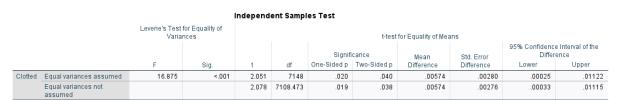


Figure 3: Independent t-test assessing clotted variable against surveillance/no surveillance.

## Discussion

This study showed a rise in thrombosis rate when a surveillance programme is suspended. Further research is needed to unpick whether this association was driven by service changes, COVID-19 or other factors during the pandemic. Current literature supports other factors such as diabetes, smoking and pre-dialysis hypotension as other factors influencing thrombosis.<sup>5</sup> It is important to bear in mind that other risks to access patency were not taken into account when assessing confounding variables and the long term effect of COVID-19 on arterial and venous

thrombosis remains unanswered. The increase in COVID-19 cases during higher rates of thrombosis would suggest a correlation however to unpick this would require a multi-centre study involving a larger sample size and the results there for need to be interpreted with caution.

It has been mentioned in a previous study about the treatment burden that patients with chronic kidney disease endure and how an increased awareness and understanding of the overall burden by health care teams is warranted.<sup>19</sup> Ultrasound surveillance is deemed to have a significant effect on the access thrombosis rate, however any reintroduction or improvement to the service should take into account patient perspective and quality of life.

Ongoing suggestions from patients regarding closer to home access clinics encouraged the team to establishing regular satellite ward rounds with outreach vascular access surgeon and nurse clinics combined. This has brought the service to the patient catchment area preventing non-dialysis day clinic appointments and reducing patient treatment burden. Since completion of this study at portable ultrasound scanner has been purchased to provide surveillance at the satellite units.

While no working environment will ever be the same and life has changed so much for everyone, there is now a certain sense of getting back to business bringing with it further challenge and change that for vascular access will hopefully be for the best.<sup>3</sup>

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#### Disclosure

This study used anonymised retrospective patient data collected from hospital clinical core IT systems that are used in routine patient care. The hospital research and development department confirmed this was a service evaluation and thus full NHS ethics committee approval was not required. Ethical approval was deemed not

required from the faculty of the University of the West of England. A Clinical Effectiveness Project was registered with the quality improvement team at the TRUST and accepted with the reference number: CE48353. No Financial support was given to the author.

Tables and Figures for Manuscript.

	Year 1 April 2019-March 2020		Year 2 April 2020-March 2021		
Total combined thrombosed access	44 (1.20)		59 (1.68)		
n (%) rate					
Total individual thrombosed access, <i>n</i> AVF (%), n AVG (%)	30 (68.2), 14 (31.8)		35 (59.4) 24 (40.6)		
Monthly	n AVF, n AVG	<i>n</i> (%) rate of	n AVF, n AVG	N (%) rate of	
combined rate of thrombosed	combined (%)	COVID-19 positive cases		COVID-19 positive cases	
access			combined (%)		
Month 1	3,3 (2.0)	0 (0.0)	<i>3,2</i> (1.5)	7 (2.2)	
Month 2	1,0 (0.3)	0 (0.0)	4,4 (2.6)	1 (0.3)	
Month 3	1,1 (0.6)	0 (0.0)	3,1 (1.3)	1 (0.3)	
Month 4	6,1 (2.2)	0 (0.0)	<i>3,2</i> (1.6)	1 (0.3)	
Month 5	<i>3,0</i> (0.9)	0 (0.0)	1,1 (0.6)	0 (0.0)	
Month 6	0,4 (1.3)	0 (0.0)	4,1 (1.7)	1 (0.3)	
Month 7	0,1 (0.3)	0 (0.0)	1,1 (0.6)	1 (0.3)	
Month 8	3,3 (1.9)	0 (0.0)	<i>5,2</i> (2.4)	9 (3.1)	
Month 9	2,0 (0.6)	0 (0.0)	2,1 (1.0)	5 (1.7)	
Month 10	2,1 (0.9)	0 (0.0)	4,5 (3.1)	7 (2.4)	
Month 11	<i>3,0</i> (0.9)	0 (0.0)	2,2 (1.4)	1 (0.3)	
Month 12	5,1 (1.9)	0 (0.0)	3,2 (1.7)	1 (0.30	

Table 1: Clotted access versus Covid-19 cases.

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