A randomized controlled trial of interrupted versus continuous suturing techniques for radiocephalic fistulas

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Objective: **Continuous suturing techniques have conventionally been used for the end-to-side anastomoses of radiocephalic fistulas (RCFs); however, primary patency rates are poor. Only 50% to 60% of RCFs ever achieve functional patency. We hypothesized that a hybrid interrupted-continuous suturing technique (as used in many microsurgical procedures) may improve outcomes in fistulas constructed from small vessels.**

Methods: **A randomized controlled trial comparing hybrid interrupted-continuous (n = 42) with continuous (n = 36) suturing techniques for RCF was undertaken. Patients were excluded if vessels were <1.8 mm in diameter or if previous ipsilateral fistula had been attempted. A priori power calculation indicated that a sample size of 78 patients was required to detect an improvement in patency from 50% to 80% ($\alpha = .05$, $\beta = .8$). The primary end point was primary patency at 6 weeks (assessed by a blinded observer for the presence of thrill and bruit). Secondary end points were immediate patency, functional patency (assessed clinically and by ultrasound) at 6 weeks, and presence of anastomotic stenosis.**

Results: **Groups were comparable for basic patient demographics, operating surgeon, and vessel diameter as measured on preoperative ultrasound (mean age, 58.9 ± 13 years; 68% male). Primary patency at 6 weeks was higher in the hybrid interrupted-continuous suturing technique group (71% vs 47%; $P = .01$). Immediate patency was also higher in the hybrid interrupted-continuous suturing technique group (93% vs 67%; $P < .001$). There was no significant difference in functional patency at 6 weeks (52% vs 36%; $P = .18$). Three patients developed an anastomotic stenosis. All were in the hybrid interrupted-continuous suturing technique group. One patient from the interrupted suturing technique cohort required re-exploration for bleeding.**

Conclusions: **A hybrid interrupted-continuous suturing technique yielded higher immediate and 6-week primary patency rates for RCF. The hybrid interrupted-continuous suturing technique may improve anastomotic compliance and reduce the narrowing and puckering that can occur on suture tightening in small-caliber vessels. Based on these findings, consideration should be given to performing hybrid interrupted-continuous anastomoses for RCFs. (J Vasc Surg 2015;62:1575-82.)**

Arteriovenous fistulas (AVFs) are the hemodialysis access modality of choice for patients with end-stage renal disease.[1,2] They are associated with a sixfold reduction in the risk of systemic sepsis[3] and lower all-cause and cardiovascular mortality than tunneled central venous catheters (TCVCs).[4]

Standard practice for autologous vascular access creation is to start distally with a radiocephalic fistula (RCF) and work up the arm to an elbow brachiocephalic fistula if initial attempts fail or wrist vessels are unsuitable.[5]

The Achilles heel of native fistulas is poor early patency.[6] Primary patency of RCF remains between 50% and 65%.[7-9] Numerous reasons for early failure and "failure to mature" have been postulated, including abnormal anastomotic hemodynamics, venous diameter, intimal hyperplasia and scarring or stenosis, and inadequate arterial inflow.[10,11] Technical factors will also invariably affect early AVF patency rates.[12] The influence of operative technique is likely to be most marked for the challenging small wrist vessels and microsurgical anastomoses using magnification with operating loupes required for RCF.[10,12,13]

A number of different operative modifications, including side-to-side anastomoses,[14,15] vein cuffs,[16] and variations in the anastomotic angle,[17] have been proposed in an attempt to improve flow dynamics and to minimize early AVF failure. All use conventional continuous suturing techniques, and none has proved particularly successful.

Other clinical fields, including free flap transfer,[18] coronary artery bypass grafts,[19] and hepatic artery reconstruction,[20,21] and small animal models[22,23] use interrupted suturing techniques (or modifications of interrupted suturing techniques with interrupted sutures for at least part of the anastomosis) for microsurgical anastomoses (with either operating microscope or surgical loupes) with excellent results. Theoretical benefits include improved anastomotic compliance and reduced puckering and luminal narrowing.[10,18]

From the Department of Renal Surgery, Western Infirmary.
Clinical Trial registration: NCT01704313.
Author conflict of interest: none.
Presented as an oral presentation at the Vascular Access Society of the Americas, Dallas, Texas, May 2-3, 2014.
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0741-5214

http://dx.doi.org/10.1016/j.jvs.2015.07.083

We hypothesized that akin to other microsurgical anastomoses, the small vessels of RCFs may benefit from interrupted suturing techniques. Our aim was to compare early patency rates of RCFs created with continuous suturing with those created with a hybrid interrupted-continuous suturing technique.

METHODS

Ethics. Ethical approval for this trial was granted by the West of Scotland Research Ethics Committee, and research has been carried out in accordance with the Declaration of Helsinki. All participants provided written informed consent.

Participants. Patients were recruited from our regional Vascular Access Centre at the Western Infirmary, Glasgow, between August 2012 and January 2014. All adult patients (older than 18 years) who were having RCFs created were eligible to participate. Patients were excluded if they were unable or unwilling to provide consent, if they had previous ipsilateral attempts at AVF creation, and if the radial artery was <1.8 mm or the cephalic vein at the wrist was <2 mm on preoperative ultrasound (without tourniquet).

Randomization. Patients were randomized in a 1:1 fashion to either hybrid interrupted-continuous or continuous suturing technique. The randomization sequence was generated using a web-based computer random sequence generator, and sequentially numbered, opaque, sealed envelopes were produced by a colleague independent of the research team.

Recruitment. Patients were approached preoperatively by a member of the research team. If willing to participate, they were assigned a study number and sealed envelope. The sealed envelope was opened by the operating surgeon in theater immediately preoperatively. The operating surgeons were independent of the research team.

Both patient and research team were blinded to the allocation. Concealment was maintained until all patients had reached the primary end point.

Operative technique. The procedures were performed by a total of eight experienced consultant vascular access surgeons (or senior trainees under consultant supervision). All surgeons had experience of performing anastomoses with both interrupted and continuous suturing techniques; however, before the study, all but one would routinely use a continuous suturing technique for creation of RCFs.

Anesthetic was provided with either supraclavicular block or local injection. All surgeons used operating loupes with 8× magnification. Standard approach to the vessels with arteriotomy was performed. The anastomoses were performed with 6.0 or 7.0 Prolene according to the surgeon's preference. For the continuous suturing technique, a stay suture was inserted at the toe of the vein, and then a single suture was run around the entirety of the anastomosis starting from the heel (Fig 1). The hybrid interrupted-continuous suturing technique also required a stay suture. Three single interrupted sutures were then placed at the heel of the anastomosis and tied before a continuous suture was used to complete the remainder of the anastomosis (Figs 1 and 2).

Outcomes. The primary end point was primary patency at 6 weeks (assessed by a blinded observer for the presence of thrill and bruit). Secondary end points were immediate patency, functional patency (assessed clinically and by ultrasound) at 6 weeks, patency at time of discharge from the hospital, and presence of anastomotic stenosis.

Primary patency at 6 weeks was assessed by blinded members of the research team. This was defined clinically as the presence of thrill and bruit confirmed by two members of the research team. Immediate postoperative patency and patency at time of discharge were also assessed clinically (presence of thrill and bruit) by the research team. Functional patency at 6 weeks was assessed by the research team both clinically (deemed suitable for cannulation by experienced dialysis nurse) and by ultrasound (>6 mm diameter, <6 mm from skin surface, flow rate >600 mL/min).[24,25] All ultrasound measurements were obtained in triplicate by a single skilled operator, and an average was obtained. Anastomotic stenosis was defined as a clinically relevant ultrasound-detected stenosis with access flow <650 mL/min[26] or peak systolic velocity ratio ≥3:1[27] and failure to mature.

Complications including need for re-exploration, bleeding, and wound infection were also recorded.

Sample size calculation. A priori power calculation determined that a total of 78 patients (39 in each arm) would be required to detect an improvement in primary patency at 6 weeks from 50% to 80% with 80% power and significance .05. Because of the short follow-up period, it was not anticipated that there would be any dropouts. However, because of organizational issues, concerns that patients may be randomized and then surgery not proceed were overcome by replacing any subject withdrawn from the study after randomization with another subject.

Statistical analysis. Results were analyzed with GraphPad Prism 6 (GraphPad, San Diego, Calif). Data were tested for normality. Assuming normal distribution, a Student *t*-test (two-tailed) was used to compare continuous data and Fisher exact test to compare categorical data. $P < .05$ was considered significant. Results are presented as mean (standard deviation) or as median (interquartile range) if not normally distributed or as a percentage of the total population.

RESULTS

Ninety-three patients were considered for participation in the study. Three were excluded (one was unable to provide informed consent; two declined participation). Ninety patients were randomized; 78 patients completed the study protocol (36 continuous sutures; 42 hybrid interrupted-continuous sutures). Surgery was canceled in eight patients because of organizational issues and in three patients for medical reasons (one developed chest pain and two had

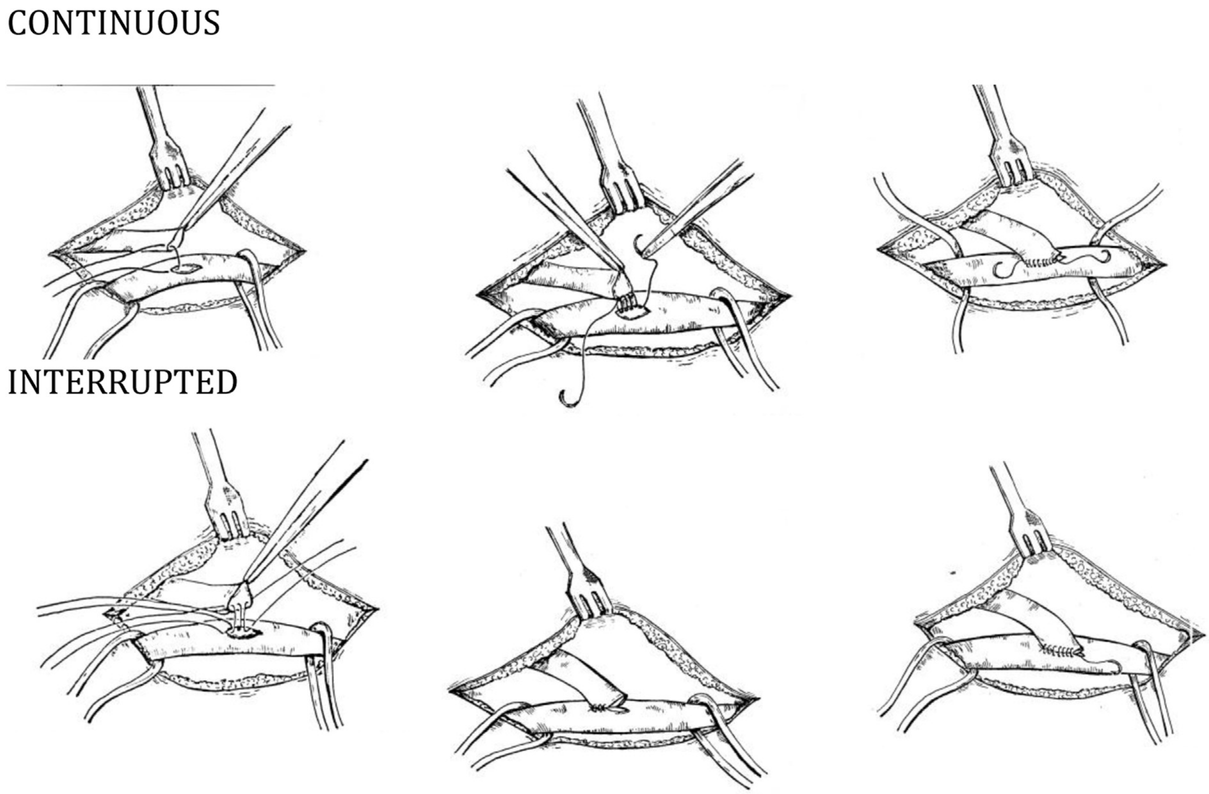

Fig 1. Diagram illustrating continuous suturing technique (*top*), in which a single suture length is used to perform the entire anastomosis, and interrupted suturing technique (*bottom*), in which three interrupted sutures are inserted first into the heel of the anastomosis (*bottom left*). These are then tied down (*bottom middle*) before another suture is used to run around the rest of the anastomosis (*bottom right*). Diagrams courtesy of Jessica Thompson, University of Dundee.

uncontrolled hypertension) after randomization, and one patient had a protocol breach, with the surgeon deciding to create a brachiocephalic fistula despite the patient's meeting the criteria for RCF and having been randomized. All 78 patients completed the study and follow-up period. The Consolidated Standards of Reporting Trials (CONSORT) diagram[28] is shown in Fig 3.

The mean age of the patients was 58.9 (13.3) years; 68% (n = 53) were male. Table I outlines basic patient demographics, comorbidities, and medications at the time of fistula creation. In general, the groups were comparable for age and sex. More patients in the hybrid interrupted-continuous cohort had peripheral vascular disease and atrial fibrillation, whereas more patients in the continuous cohort had adult polycystic kidney disease as their cause of renal failure. There was no significant difference between the groups with regard to dialysis status, anesthetic technique, or operating surgeon.

Preoperative vessel diameters and radial artery blood flow were comparable between the two cohorts, with a mean radial artery diameter of 2.16 (0.3) mm in the continuous cohort and 2.14 (0.2) mm in the hybrid interrupted-continuous cohort ($P = .71$) and mean cephalic vein diameters of 2.59 (0.6) mm in the continuous cohort and 2.41 (0.4) mm in the hybrid interrupted-continuous cohort ($P = .14$; Table II). Mean preoperative radial artery blood flow was also comparable between the two cohorts (44.3 [13] vs 43.7 [12.9] mL/min; $P = .76$).

Primary patency at 6 weeks was higher in the hybrid interrupted-continuous suturing technique group (71% vs 47%; $P = .01$). Immediate patency was also higher in the interrupted suturing technique group (93% vs 67%; $P < .001$). There was no significant difference in functional patency at 6 weeks (52% vs 36%; $P = .18$; Table III).

Three patients developed an anastomotic stenosis. All were in the hybrid interrupted-continuous suturing technique group. One patient in the continuous suturing cohort developed evidence of a venous outflow stenosis (5 cm above the anastomosis) during the follow-up period. One patient from the hybrid interrupted-continuous suturing technique cohort required re-exploration and ligation for bleeding from the suture line on day 3 postoperatively. Three patients in the continuous suturing technique arm were re-explored immediately because of absence of thrill and bruit. Patency was restored in one of the three. Eight patients required surgical revision after assessment at 6 weeks because of inadequate maturation and lack of functional patency (three anastomotic stenoses, all in the

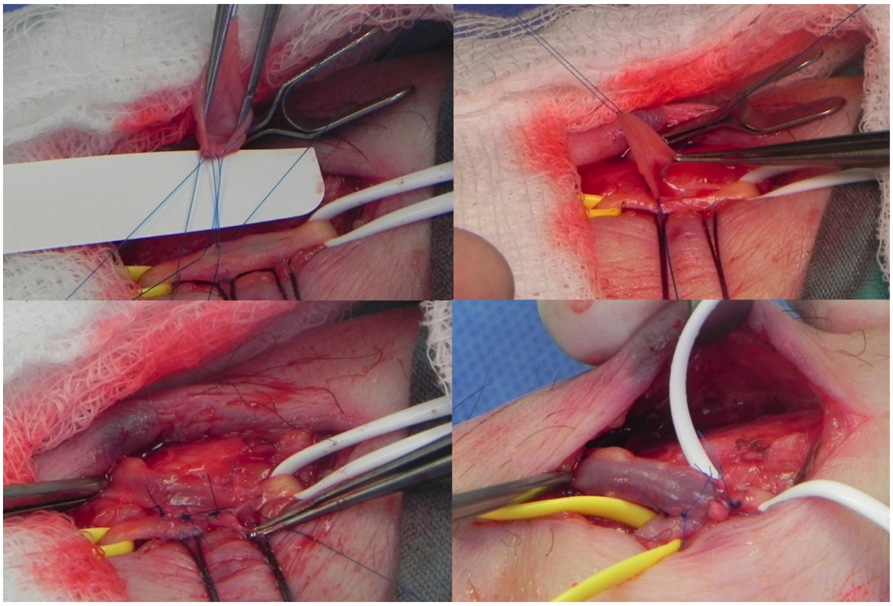

Fig 2. Interrupted suturing technique. *Top left,* Three interrupted sutures at heel of anastomosis. *Top right,* Interrupted sutures at heel of anastomosis tied down. *Bottom left,* Continuous sutures used to complete anastomosis. *Bottom right,* Blood flow restored with dilation of anastomosis.

interrupted arm; two superficializations; three ligations of collaterals). The venous outflow stenosis was successfully treated with angioplasty.

DISCUSSION

Our results demonstrate superiority of a hybrid interrupted-continuous suturing technique for the creation of RCFs with improved early (6 week) primary patency rates compared with continuous techniques (71% vs 47%; $P = .01$). There was no significant difference in functional patency at 6 weeks (52% vs 36%; $P = .18$). To our knowledge, this is the first clinical study to demonstrate benefit of a specific suturing technique in AVF creation.

Lately there has been increasing interest in involved and technically advanced vascular access procedures for patients with complex vascular access needs, eg, central venous stenosis.[29] Such procedures are time-consuming, costly, and associated with significant morbidity, and they generally have poor outcomes.[30] Similarly, many targets and tariffs (such as those employed by the National Health Service in England and Wales) focus on optimizing prevalent vascular access in long-term hemodialysis patients.[31] Conversely, we believe that optimizing native AVF use in incident patients new to hemodialysis is simpler and more cost-effective and may prevent progression to complex "end-stage" vascular access cases for the future. Locally, root cause analysis has determined that one of the principal reasons for incident patients commencing hemodialysis through a TCVC is failure of the initial AVF to mature.[32] Patients who start hemodialysis through a TCVC are more likely to continue with a long-term TCVC (with the patient's choice and loss of future access options being cited as potential causes)[33]; therefore, optimizing early AVF patency and incident vascular access is essential to minimize TCVC use. In this study, we have demonstrated that simple modifications to the anastomotic suturing technique can improve early patency.

Interrupted suturing techniques are well established and used routinely in clinical practice for many microsurgical anastomoses in plastic surgery and maxillofacial surgery.[18] However, much of the evidence derives from small animal models.

Schlechter and Guyuron[22] demonstrated a reduced rate of anastomotic stenosis with interrupted suturing techniques in their rabbit femoral artery model. Similarly, Tozzi et al[34] demonstrated increased anastomotic luminal diameter with interrupted suturing in their bovine model of internal mammary artery grafting, and Gerdisch et al[19] showed improved anastomotic compliance, reduced pulsatility indices, and increased diastolic and peak flow through the vessels in their porcine model of coronary artery bypass grafting. The ability of the anastomosis to expand between the interrupted sutures (rather than tightening and puckering as occurs with continuous techniques) permits distention of the anastomosis.[10] This is particularly important in the vessels of RCF, which are often <2 mm.[12,35] In addition, improved anastomotic compliance and reduced compliance mismatch have been found by other authors to improve hemodynamics and are believed to reduce peri-anastomotic neointimal hyperplasia.[10,36,37] Notably, however, Joos et al[38] failed to demonstrate any histologic differences at the anastomosis of rodent femoral vein 3 weeks after anastomosis with interrupted and continuous microsuturing techniques. Ongoing work at Hull

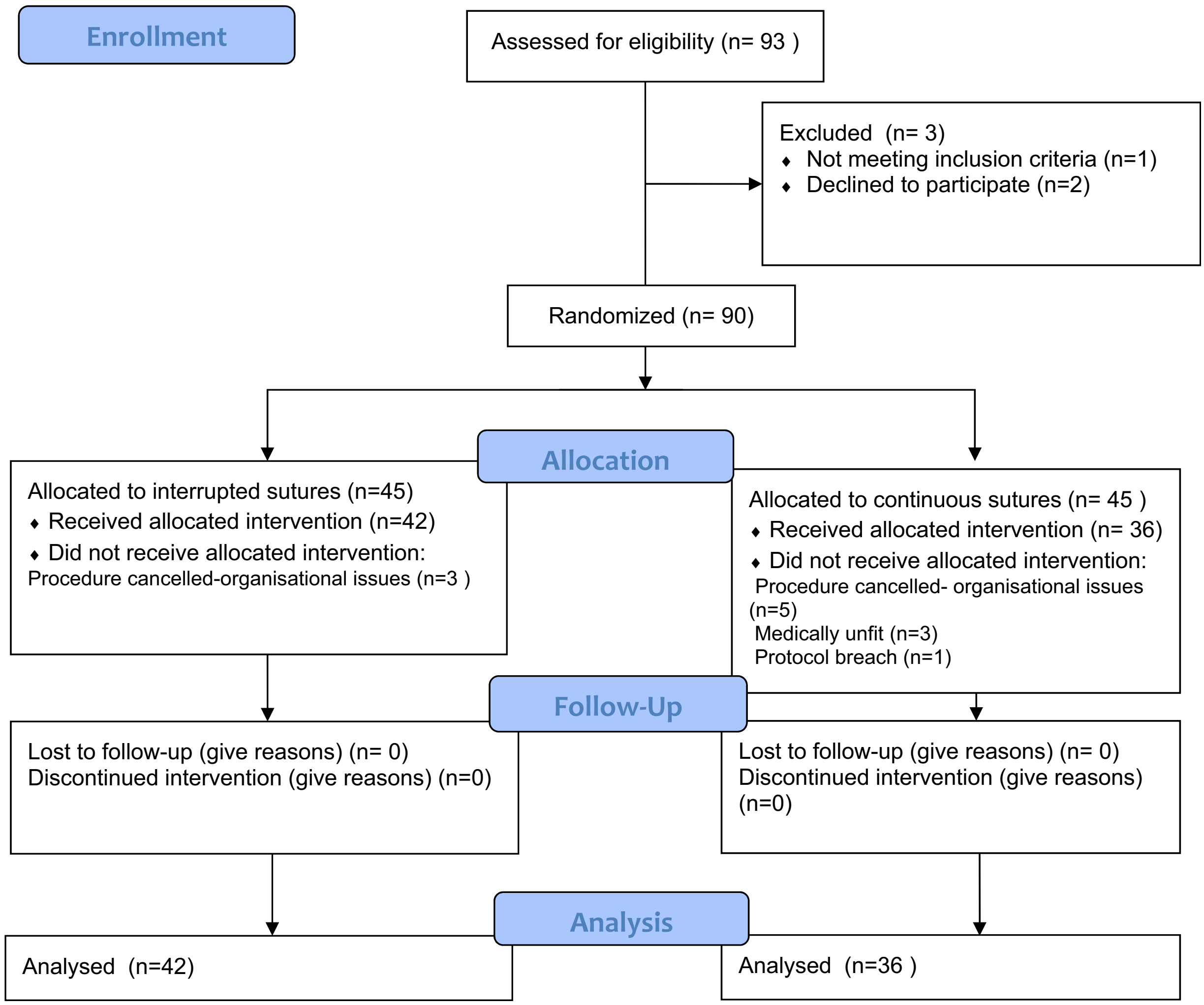

Fig 3. Consolidated Standards of Reporting Trials (CONSORT) flow diagram outlining participant flow.

University evaluating the relationship between anastomotic compliance and histologic changes at AVF anastomoses in humans may better clarify this in the future.[39]

Several clinical studies have demonstrated benefit of interrupted suturing techniques (or modifications of the interrupted suturing technique) for hepatic artery reconstruction in liver transplantation[20] and coronary artery bypass grafting.[40] Other authors have shown no difference in patency in animal models.[23,41] The sole previous clinical study of suturing technique for RCF showed no benefit of interrupted over continuous suturing technique.[35] The numbers of patients, however, were small (only 20 patients in each arm), and follow-up was >3 years, potentially missing the important differences in early patency related to the anastomotic technique and risking confounding factors, not least of which are neointimal hyperplasia and venous outflow stenosis at sites of needle injury.[42] Studies of side-to-side anastomoses in both RCF and brachiocephalic fistula are small and retrospective. Nevertheless, these studies have indicated that despite the obvious improved flow volume across the anastomosis, AVF patency is not improved compared with simple end-to-side anastomoses.[14,15] Zeebregts et al[43] demonstrated improved patency and fewer anastomotic stenoses in AVFs created with interrupted titanium clips over continuous sutures. They cite superior hemodynamics and improved healing pattern with the interrupted clipping technique as an explanation. In our cohort, the incidence of anastomotic stenosis was actually higher in the hybrid interrupted-continuous technique arm. Three patients in the interrupted suturing technique arm had an anastomotic stenosis. All three went on to have successful surgical revision of the AVF, ultimately resulting in a functionally patent AVF. We hypothesize that the patients in the hybrid interrupted-continuous technique arm of the study who developed an anastomotic stenosis may be akin to those in the continuous technique arm who had an early thrombosis, but they retained patency (albeit with an anastomotic

Table I. Basic patient demographics, comorbidities, and medications

	Continuous	*Interrupted*	P *value*
Age, years	57.7 (15.2)	60.0 (12.9)	NS
Male	69 (25)	67 (28)	NS
Cause of renal failure			
Diabetic nephropathy	25 (9)	21 (9)	NS
APKD	22 (8)	2 (1)	<.001
Glomerulonephritis	6 (2)	14 (6)	<.01
Reflux nephropathy	8 (3)	4 (2)	.11
Hypertensive nephropathy	3 (1)	7 (3)	.04
IgA nephropathy	3 (1)	19 (8)	<.001
Other	14 (5)	24 (10)	<.01
Unknown	19 (7)	7 (3)	<.01
Comorbidities			
Diabetes	36 (13)	31 (13)	NS
Hypertension	28 (10)	43 (18)	.04
Atrial fibrillation	14 (5)	5 (2)	<.01
Peripheral vascular disease	0 (0)	9 (4)	<.01
Ischemic heart disease	17 (6)	19 (8)	NS
Medications			
Antihypertensives (No.)	2 (1.3)	2 (1.4)	NS
Beta blocker	53 (19)	57 (24)	NS
Aspirin	28 (10)	17 (7)	.03
Clopidogrel	14 (5)	12 (5)	NS
Warfarin	3 (1)	12 (5)	.01
Statin	39 (14)	43 (18)	NS
Dialysis status			
Predialysis	53 (19)	57 (24)	
Hemodialysis	44 (16)	38 (16)	
Peritoneal dialysis		2 (1)	
Failing transplant	3 (1)	2 (1)	NS
Surgeon			
1	14 (5)	31 (13)	
2	19 (7)	19 (8)	
3	6 (2)	7 (3)	
4	8 (3)	9 (4)	
5	17 (6)	5 (2)	
6	11 (4)	7 (3)	
Others	25 (9)	21 (9)	NS
Anesthetic technique			
Local anesthetic	56 (20)	52 (22)	
Supraclavicular block	42 (15)	36 (15)	
General anesthetic	3 (1)	12 (5)	NS

APKD, Adult polycystic kidney disease; *IgA,* immunoglobulin A; *NS,* not significant.
Results are presented as a percentage of the total population, % (n).

Table II. Radial artery and cephalic vein diameters and radial artery blood flow preoperatively

	Continuous	*Interrupted*	P *value*
Radial artery, mm	2.16 (0.27)	2.14 (0.24)	.71
Cephalic vein, mm	2.59 (0.61)	2.41 (0.43)	.14
Blood flow in radial artery, mL/min	44.3 (13.2)	43.7 (12.9)	.76

Data are presented as mean (standard deviation).

Table III. Comparison of patency rates

	Continuous	*Interrupted*	P *value*
Patency at 6 weeks	47 (17)	71 (32)	.01
Functional patency at 6 weeks	36 (13)	52 (22)	.18
Immediate patency	93 (39)	67 (24)	<.01
Thrill on discharge	83 (35)	53 (19)	<.01
Bruit on discharge	88 (37)	56 (20)	<.01

Results are presented as a percentage of the total population, % (n).

stenosis), perhaps because of improved hemodynamic properties of the anastomosis.

One of the criticisms of the interrupted suturing technique is that it is more time-consuming.[23] Our interrupted technique is similar to the combined interrupted-continuous technique described by Lykoudis et al,[44] using interrupted sutures around the heel of the anastomosis and then continuous sutures for the rest. Other authors who report an interrupted suture technique commonly use modifications of this with partial interrupted and partial continuous sutures.[20,21] By use of this combined technique, the operating time may be reduced.[44]

In addition, there is a theoretical risk that interrupted sutures could bleed more from the gaps between suture lines. Chen et al[23] found a significantly increased bleeding time and blood loss from interrupted suture lines in their rabbit femoral artery model. Alternatively, it could be argued that the improved anastomotic compliance of the interrupted anastomosis actually improves contraction and may reduce the risk of bleeding.[10] In our cohort, the single bleeding complication was in the hybrid interrupted-continuous suturing technique arm. Bleeding from the anastomosis was identified when the patient underwent re-exploration 3 days postoperatively and the fistula required ligation. The exact bleeding point could not be identified. We postulate that this bleed was a sporadic event; however, no clear conclusions can be drawn from this as our study was inadequately powered to detect complications.

The primary end point for this study was primary patency at 6 weeks as assessed by two independent blinded members of the research team (an experienced clinician and a senior dialysis nurse). An early end point was chosen to minimize the multiple confounding factors (eg, cannulation technique, outflow stenosis) that are inherent in evaluating vascular access. We believed that a clinically relevant end point for the study was essential. Ideally, primary patency evaluated by ability to sustain dialysis would have been chosen as the end point. However, because of the large number of patients who were predialysis at the time of AVF creation, this was not feasible. It is acknowledged that clinician assessment could be open to observer bias; however, both observers were blinded, and there was 100% agreement between independent assessors for both patency and functional patency, indicating good validity and reproducibility. Furthermore, confirmation of patency by defined ultrasonographic criteria provides a second quantitative measurement of functionality.

As with any operative technique, both the hybrid interrupted-continuous and continuous suturing techniques in this study are susceptible to surgeon bias. Nearly half of the AVFs created in this study were formed by only two surgeons. One routinely performed RCF using hybrid interrupted-continuous technique; the other routinely used a continuous technique. There was no significant difference in the relative proportions of interrupted and continuous technique AVFs created by any surgeon, and the study was underpowered to evaluate outcomes by individual surgeons. However, it is recognized that the technical abilities and preferences of individual surgeons could skew results.

CONCLUSIONS

We have presented the results of a single-center randomized controlled trial comparing hybrid interrupted-continuous to continuous suturing techniques for creation of the radiocephalic AVF anastomosis. We have demonstrated superiority of the hybrid interrupted-continuous suturing technique with improvement in the primary outcome (patency at 6 weeks). Based on these findings, consideration should be given to performing hybrid interrupted-continuous anastomoses for RCFs.

AUTHOR CONTRIBUTIONS

Conception and design: EJ, DK
Analysis and interpretation: EA
Data collection: EA, MA
Writing the article: EA
Critical revision of the article: EA, DK
Final approval of the article: EA, EJ, MA, DK
Statistical analysis: EA
Obtained funding: Not applicable
Overall responsibility: DK

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Submitted Dec 16, 2014; accepted Jul 23, 2015.