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S-shaped versus conventional straight skin incision: Impact on primary functional maturation, stenosis and thrombosis of autogenous radiocephalic arteriovenous fistula
Impact of incision on maturation, stenosis & failure of RCAVF. Study design: Prospective observational comparative

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HIGHLIGHTS

- S-shaped skin incision is an alternative to the conventional skin incision for creation of radiocephalic arteriovenous fistula (RCAVF).
- This approach permits better exposure for both vessels and minimise the need for extensive mobilisation of cephalic vein.
- S-shaped skin incision is associated with lower incidence of stenosis within the maturation period.

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ABSTRACT

Introduction: The objective of this study is to test the null hypothesis that an S-shaped surgical incision versus conventional (straight) skin incision in the creation of autogenous radiocephalic arteriovenous fistulas (RCAVFs) have no impact on the primary end-point of primary functional maturation and secondary end points of stenosis and thrombosis.
Methods: A prospective observational comparative consecutive study with intention-to-treat on individuals undergoing only radiocephalic arteriovenous fistula (RCAVFs) over a period of 12 months was conducted. Variables on patient's demographics, comorbidities, anesthesia type, mean arterial blood pressure, thrill, laterality, cephalic vein and radial artery diameter were collated. The test of probability was assessed through Chi-Square, Kaplan-Meier survival estimator and Log-Rank analysis.
Results: Total of n = 83 individuals with median age of 67 years (IQR, 20–89) and male predominance 83% during this period were subjected to RCAVF formation. Total of n = 45 patients in straight skin incision were compared to n = 38 individuals in S-shaped group. Despite equal prevalence of demographics, comorbidities, anesthesia type, mean arterial blood pressure (MAP), thrill, laterality, cephalic vein and radial artery diameter ($p > 0.05$) higher incidence of juxta-anastomotic stenosis was noted in the straight skin incision group ($p = 0.029$) in comparative and survival analysis (Log-Rank, $p = 0.036$). The maturation of the entire cohort was 69% (S-shaped 76% vs. straight group 62%) ($p > 0.05$).
Conclusion: The outcome of this study demonstrates that S-shaped surgical skin incision is associated with a lower incidence of stenosis in comparison to straight incision type in RCAVF formation.

1. Introduction

The Brescia-Cimino arteriovenous fistula is the gold standard and the primary vascular access choice for hemodialysis patients over the past 50th years [1]. Failure of primary functional maturation (FM) remains a major obstacle and ranges from 10% to 70% in

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different centers [2]. Their failure is associated with significant reliance on temporary dialysis, use of bridging catheters, use of prosthetic conduits; possible central venous stenosis and an overall increase in cost and utilisation of health care resources [3]. To date, various studies have evaluated the impact of different variables on the primary FM of radio-cephalic arteriovenous fistulae (RCAVF) [4,5]. However, only one study to date has evaluated the impact of surgical skin incision on the FM and failure of RCAVF [6]. This study assessed the impact of transverse incision to that of conventional type in practice and was associated with poor outcomes [7].

Traditionally a straight incision given midway between the radial artery and cephalic vein, described by Brescia-Cimino, is the commonest adopted technique worldwide. However, in this approach, the outflow component (cephalic vein) remains directly under the incision line. It has been suggested that tension as a consequence of wound approximation, local inflammatory changes (healing process) and extracellular matrix deposition might result in outflow stenosis and/or thrombosis. In addition, extensive mobilisation of the cephalic vein in conventional method could also result in proximal twisting of the vein on its pedicle [8]. Given majority of stenotic sites are within the 2–3 cm of cephalic vein and from anastomosis site, perhaps a different type of skin incision (S-shaped) might prove beneficial in reducing such adverse events in practice [8].

Therefore, it was hypothesised (null hypothesis) that S-shaped incision in comparison to the conventional (straight skin) method has no impact on the primary end point of functional maturation (FM) and secondary end point of stenosis and thrombosis of autogenous RCAVF.

2. Material & methods

A prospective observational comparative study with intention to treat in (consecutive) patients undergoing only radiocephalic arteriovenous fistula (RCAVFs) at our unit, from 1st of May 2015 to 1st of May 2016 was conducted. Variables included, incision type (s-shaped versus straight incision) (Fig. 1) (Fig. 2) patient's demographics (age, gender), anatomical variance (cephalic vein, radial artery diameter, laterality), comorbidities (Diabetes mellitus (DM), Ischemic heart disease (IHD), congestive cardiac failure (CHF), hypertension (HTN), hypercholesteremia), perioperative variables (anesthesia type (local versus general anesthesia)), presence of intraoperative thrill and/or not) and mean arterial blood pressure (MAP). The primary end point of the study was set at primary functional maturation (FM). The secondary end point was set at the end point of stenosis and thrombosis.

The patients were subjected to two groups of S-shaped and straight incision depending on surgeon's preference (two surgeons)

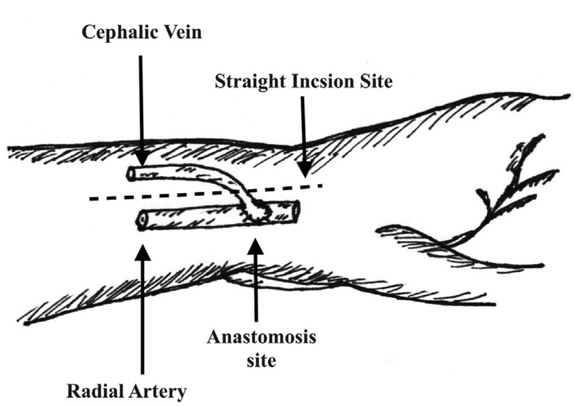

Fig. 1. Conventional straight skin Incision, demonstrating the position of the incision to that of cephalic vein, radial artery and anastomosis on a left hand.

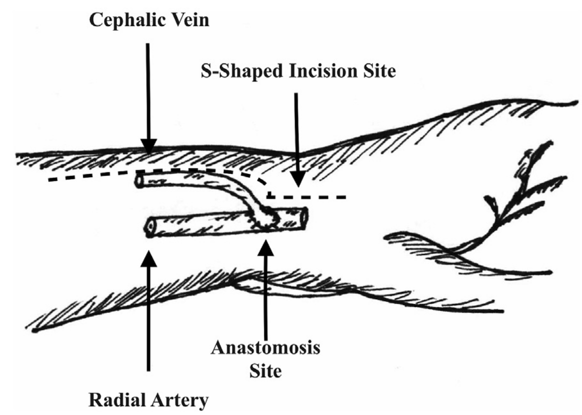

Fig. 2. S-Shaped skin incision, demonstrating the position of the incision to that of cephalic vein, radial artery and anastomosis on a left hand.

of incisions (S-shaped versus straight). In our center, one surgeon performs S-shaped and other, straight incision with equal amount of experience in renal access surgery. The allocation process started from the time of referral (renal physicians) and in preoperative consultation stage. This study was performed with accordance to declaration of Helsinki. The permission to access the renal registry data and this study was granted through clinical audit number CA13-225 obtained from the local trust.

2.1. *Definitions*

1. Functional maturation was defined against the “Rule of 6's” assessed clinically and with duplex ultrasonography at 6 weeks' post RCAVF formation, with a depth of not more than 0.5–0.6 cm from skin and diameter (main body of fistula) of 6 mm with a flow rate of 600 ml/min and length of 5–6 cm for successful two-needle cannulation and dialysis [9].
2. Stenosis was defined as reduction in the diameter of the vessel by at least >50% and more resulting in reduction of access flow or in measured dialysis dose [10,11].

2.2. *Standards*

1. The cephalic vein was considered suitable if the “Tap test” (application of tourniquet proximally and percussion of the vein with fingers for vibration across the course of the vein) was positive and the vein was continuous to the median cubitan fossa and/or cephalic vein of arm directly or in directly with a consistent diameter and/or more throughout. Cephalic vein was assessed in non-augmented (no tourniquet) state.
2. The radial artery was used and assessed further with ultrasound only if “Allen's test” was normal (positive) indicating adequate blood flow in ulnar artery and palmer arch. The radial artery was also assessed for hemodynamic studies (flow and stenosis) and not used for RCAVF if changes were noted [12].
3. Preoperative duplex of cephalic vein and radial artery, assessed the internal diameter of both vessels with linear transducer of 5–7 Mhz with arm position fully rested at 45–60° [12].
4. Comorbidities were categorized and defined in accordance with definitions provided by world health organization (WHO) [13].
5. All fistulas were created by an end (cephalic vein)-to-side (radial artery) anastomosis using 2.5× magnifying lenses

with 6/0 monofilament polypropylene continuous suture from heel to base with parachute technique and a single knot.
6. All incisions were closed with 3/0 Vicryl rapid and glue.
7. The angle of anastomosis was set at no less than 30° and no greater than 65° degrees.
8. The arteriotomy length was limited to 4 mm.
9. No intraoperative and/or postoperative heparin or any other antiplatelet or anticoagulation therapy was used [14].
10. The local anesthesia was 2% lignocaine with adrenaline on preoperative marked area (straight incision between vein and artery) to avoid damaging the vein during its infiltration.
11. Follow-up was set on 1st, 4th and 6th week of RCAVF creation.

2.3. Statistical analysis

All continuous variables were reported as median with their corresponding interquartile ranges (IQR) and categorical variables as percentages. The continuous data on cephalic vein and radial artery diameter were reorganized to form a categorical variable based on cut-offs obtained via the coordinates on a receiver operator curve (ROC). Diameter at best sensitivity and 1-specificity was taken to be the optimal cut-off diameter. The relative proportions of one group (straight incision) with their variable against independence of the second group (S-shaped) and the test of probability (*p* value) was conducted using two tailed Chi-square test on the end point of primary functional maturation (FM) (Table 1). Subgroup analysis was performed using Kaplan-Meier estimator to assess the impact of incision type (S-shaped vs. Straight) on the end point of stenosis and thrombosis respectively. The null hypothesis (*p* value) was assessed using Log-Rank test on each end point (Fig. 3) (Fig. 4). Outcome was considered statistically significant if the *p*-value was ≤ 0.05. All statistical analyses were carried out using the Statistical Package for the Social Sciences (SPSS) version 20, IBM.

3. Results

Total of n = 83 individuals were subjected to RCAVF formation during this period (1-year). The median age of the entire cohort was 67 years (IQR, 20–89) with male predominance 83% (n = 67/83). Majority of the operations were performed under local anesthesia 98% (n = 82/83) and on the non-dominant hand (left-side) 83% (n = 69/83). Primary functional maturation (FM) occurred in 69% (n = 57/83), stenosis was detected in 14% (n = 12/83) and thrombosis in 15.3% (n = 13/83). The most common comorbidity was hypertension (n = 57/83) and the least common was ischemic heart disease 15.6% (n = 13/83). The receiver operator curve for both vessel diameters at three decimal points for the best sensitivity and 1-specificity was 1.7 mm.

3.1. Straight incision versus S-shape

Total of n = 45 patients were in the straight skin incision and n = 38 patient in S-shaped group. Both groups exhibited similar demographics, comorbidities, mean arterial blood pressure (MAP), presence of a thrill and/or not, laterality, cephalic vein and radial artery diameter ($p > 0.05$). This pattern was also noted in the incidence of maturation (S-shaped 76% vs. straight group 62% ($p > 0.05$) and thrombosis (S-shaped 13% vs. straight group 18%) ($p > 0.05$). However, higher incidence of juxta-anastomotic stenosis was noted in the conventional group (straight skin incision) once assessed through comparative analysis (S-shaped 5.3% vs. straight

Table 1
Comparative group analysis (two-tailed; Chi-Square) of two groups on all variables and endpoints.

Variables		Straight incision		S-Shaped Incision		*P* value
		n	%	n	%	
Gender	Female	8	17.8%	8	21.1%	0.706
	Male	37	82.2%	30	78.9%	
Age at Surgery	18-65 years	18	50.0%	16	44.4%	0.637
	>65 years	18	50.0%	20	55.6%	
Local or General Anaesthetic	Local	44	97.8%	38	100.0%	0.355
	General	1	2.2%	0	0.0%	
Thrill/No Thrill/pulse	None	3	6.7%	7	18.4%	0.133
	Thrill	42	93.3%	30	78.9%	
	Pulse	0	0.0%	1	2.6%	
Hypertension (HTN)	No HTN	10	23.3%	12	33.3%	0.320
	HTN	33	76.7%	24	66.7%	
Cholesterol Levels	No Cholesterol	17	39.5%	16	43.2%	0.737
	Cholesterol	26	60.5%	21	56.8%	
Ischaemic Heart Disease (IHD)	No IHD	35	81.4%	31	86.1%	0.573
	IHD	8	18.6%	5	13.9%	
Diabetes Mellitus (DM)	No DM	30	73.2%	29	80.6%	0.445
	DM	11	26.8%	7	19.4%	
Laterality	Left	39	86.7%	30	81.1%	0.491
	Right	6	13.3%	7	18.9%	
Vein Dimeter (in mm)	Up to 1.70 mm	19	43.2%	14	36.8%	0.559
	>1.70 mm	25	56.8%	24	63.2%	
Artery Diameter (in mm)	Up to 1.70 mm	28	63.6%	18	47.4%	0.139
	>1.70 mm	16	36.4%	20	52.6%	
Mean Arterial Pressure (MAP)	Up to 113 mmHg	19	57.6%	23	67.6%	0.394
	>113 mmHg	14	42.40%	11	32.4%	
Maturation	Not Matured	17	37.8%	9	23.7%	0.168
	Matured	28	62.2%	29	76.3%	
Thrombosis	No Thrombosis	39	86.7%	31	81.6%	0.525
	Thrombosis	6	13.3%	7	18.4%	
Stenosis	No Stenosis	35	77.8%	36	94.7%	**0.029**
	Stenosis	10	22.20%	2	5.3%	

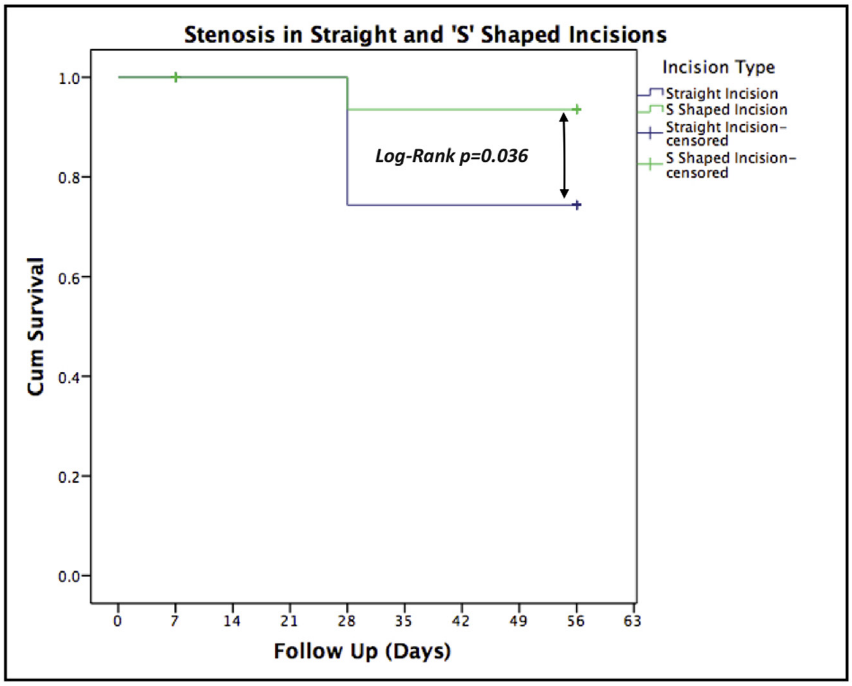

Fig. 3. Kaplan-Meier and Log-Rank analysis for the end point of stenosis.

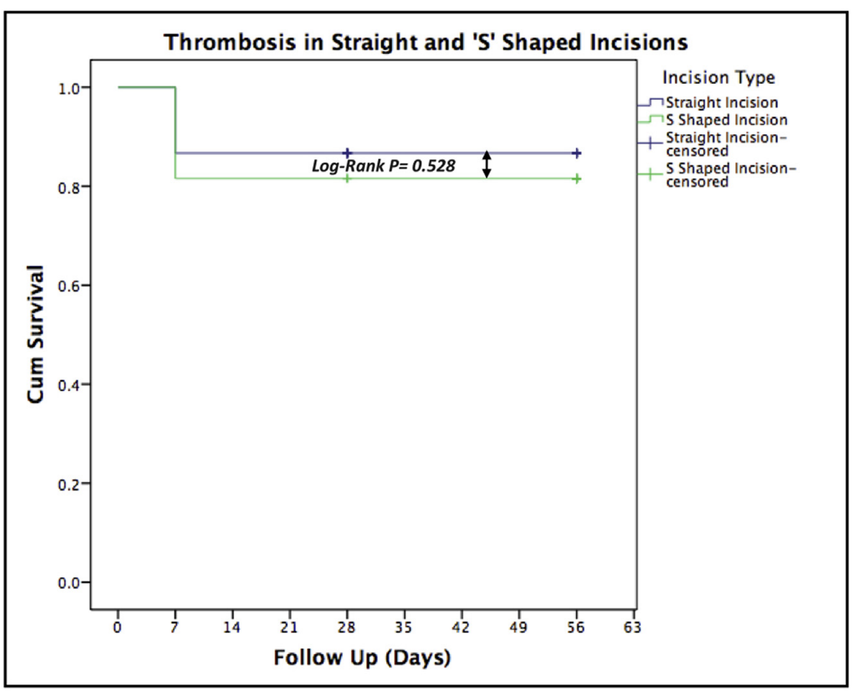

Fig. 4. Kaplan-Meier and Log-Rank analysis for the end point of thrombosis.

group 22%) ($p = 0.029$). Subgroup analysis demonstrated similar outcome once assessed through Kaplan-Meier estimator and Log-Rank analysis (log-rank, $p = 0.036$).

4. Discussion

Since the introduction of the RCAVFs in 1966, various research has been conducted to stratify factors that contribute to the failure of primary FM in RCAVFs [15–17]. Modification of anastomosis techniques and their angle in conjunction with a better understanding of volumetric parameters (pressure & flow) has been attributed to a higher incidence of primary FM in practice. Maturation is the outcome of positive vascular remodeling, however their impairment could result in early stenosis and/or thrombosis. It has been established that neo-intimal hyperplasia, inward negative and outward positive venous remodeling play a vital role in this process [18].

It has been recognized that endothelial cells within the vessel wall are important mediators of intracellular signaling. Their exposure to sheer stress as a consequence of inflow, stimulates vascular smooth muscle cells and results in intimal hypertrophy and thickening [19–21]. However, the entire process depends on the distensibility of the cephalic vein and the direction of the intimal hyperplasia [tunica intima (inward) versus tunica media (outward)] [19–21]. Almost 80% of stenosis in RCAVF fall within 2–3 cm of cephalic vein segment away from the anastomotic site. In conventional (straight) incision as demonstrated in Fig. 1, this section of the vein falls directly under the skin incision site. Thus, extrinsic pressure at this focal point with resultant lack of vein dilatation coupled with inward negative vascular remolding (intimal thickening) could contribute to a higher incidence of stenosis and if not identified early thrombosis [22].

Another contributing factor in such circumstances is related to the process of wound healing within the maturation period. It has been noted that during the inflammatory and proliferation phase of wound healing, which could last to up to 60 days, edema, collagen and extracellular matrix deposition at the straight incision site could result in intrinsic tension, extrinsic pressure, impingement and possible focal stenosis of the cephalic vein [23,24].

In contrast to the conventional skin incision, the outflow component (cephalic vein) of RCAVF remains under the medial flap and not directly under the incision site. This also inhibits the partial untoward twist of the cephalic vein on its longitudinal axis that is commonly associated with extensive mobilisation noted in straight incision. This is mainly due to the fact that in S-shaped incision, the line of incision exposes both vessels and extensive mobilisation for approximation and anastomosis is not required [7]. The combination of aforementioned factors could explain why a higher incidence of (cephalic vein) stenosis was noted in the straight group both in group ($p = 0.029$) and survival estimates analysis ($p = 0.036$). Furthermore, this process could explain why transverse incision in the past has also demonstrated very poor outcome in practice [25].

The presence of equal, favorable and comparable prevalence of patient demographics, comorbidities, anesthesia type, laterality, mean arterial blood pressure (MAP) and anatomical variance, along with their exposure to set and replicable perioperative standards has substantially reduced the possible impact of performance bias and their causal link to the end point of maturation, stenosis and thrombosis. Therefore, inference from this observational comparative series is unlikely to have been influence by any other factor than that of incision type. However, the outcome of this study is only applicable to those RCAVFs within maturation period that were created by continuous anastomosis from heel to base and in end (cephalic vein) to side (radial artery) format with parachute technique. In our unit, we do not use the “the smooth loop technique” of Karmody and/or Tellis technique for anastomosis [26,27]. The angle and the length of the venotomy and arteriotomy was defined by the longitudinal axis of the artery and was to limited to 30–65° and 4 mm respectively [7]. The overall FM of 69% achieved in both groups appears to in be favor and greater than some reports in the literature [2]. Finally, in an era, where failure of FM has significant cost, medical and psychological implications, optimization of primary FM remains vital and every effort should be made to get it done and right the first time.

4.1. Strength and limitations

To the best of our knowledge, this is the first study that has assessed the role of two different skin incisions, apart from transverse incision, on the primary functional maturation, stenosis and thrombosis of autogenous RCAVFs in the literature. The outcome of this study suggests that alternative skin incision (s-shaped) is associated with lower incidence of stenosis and could be used in confidence. Due to similar characteristics of the evaluated groups, this observational comparative study remains internally valid and robust.

However, due to the limited number of individuals the power of the study remains an issue and external validity would have benefited greatly from a higher number of patients. It is possible that variance in transducer (ultrasound) choice could also pose some bearing on the internal measurement of the vessel diameters used in the creation of RCAVFs at our center, especially considering that the theoretical axial resolution of a 7 Mhz transducer is approximately 0.3 mm. However, the choice of ultrasound machine and patient arm position should not significantly alter the measurements in practice. This type of incision might prove useful in construction of other types of fistula such as brachiocephalic or high radio cephalic ones.

5. Conclusion

The outcome of this study suggests that alteration in skin incision from conventional (straight incision) to S-shaped could prove beneficial in reducing stenotic complications during RCAVF maturation. Future research might need to consider this an additional factor in their evaluation.

Ethical approval

The permission to access the renal registry and this project was granted through clinical Audit Number CA13-225 from the local trust as part of service improvement project.

Sources of funding

None.

Author contribution

A.Kordzadeh: Study design, data collection, Illustrations, writing and final revision.

A.Askari: Statistical Analysis, Writing and revision.

Yiannis Panayiotopolous: Supervision, writing and revision of the paper.

Conflicts of interest

Authors declare no conflict of interest.

Research registration unique identifying number (UIN)

The permission to access the renal registry and this project was granted through clinical Audit Number CA13-225 from the local trust as part of service improvement project.

Guarantor

A.Kordzadeh.

Presentation

The preliminary outcome of this study was presented as a poster at Charring Cross International Vascular Symposium, Vascular access, London, UK, 2017.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.amsu.2017.08.018.

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