Study Protocol

A Randomized Controlled Study on the Efficacy of Ultrasound-Guided Fistuloplasty in Comparison to Fluoroscopy-Guided Fistuloplasty in Patients with Arteriovenous Access Flow Dysfunction

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Study site/s:
Hospital Kuala Lumpur.
University Malaya Medical Centre.

Contents

List of Abbreviations

AV	Arteriovenous
AVF	Arteriovenous fistula
C-PTA	Conventional percutaneous transluminal angioplasty
CI	Confidence interval
DCB	Drug-coated balloon
HD	Haemodialysis
HKL	Hospital Kuala Lumpur
n	Number
OD	Odds ratio
PIS	Patient information sheet
POBA	Plain old balloon angioplasty
PSV	Peak systolic velocity
PTA	Percutaneous transluminal angioplasty
SD	Standard deviation
SPSS	Statistical Package for the Social Sciences
TBD	To be determined
UG-PTA	Ultrasound-guided percutaneous transluminal angioplasty
UMMC	University Malaya Medical Centre
USG	Ultrasonography
VF	Volume flow

Research Synopsis

Study title	A randomized controlled study on the efficacy of ultrasound-guided fistuloplasty in comparison to fluoroscopy-guided fistuloplasty in patients with arteriovenous access flow dysfunction.
Study Population	All adult patients with arteriovenous access flow dysfunction in Hospital Kuala Lumpur and University Malaya Medical Centre during the period 1 July 2023 – 30 June 2024.
Study Design	A randomized controlled study. Selected subjects will be randomized into ultrasound-guided fistuloplasty and fluoroscopy-guided fistuloplasty groups in a ratio of 1:1
General Objective	To investigate patencies in patients with arteriovenous access flow dysfunction receiving ultrasound-guided fistuloplasty versus fluoroscopy-guided fistuloplasty at 6 months
Specific Objectives	a. To investigate patencies in patients with arteriovenous access flow dysfunction receiving ultrasound-guided fistuloplasty versus fluoroscopy-guided fistuloplasty at 6 months, b. To capture data regarding variables that may affect patency of arteriovenous access flow dysfunction post ultrasound-guided fistuloplasty versus fluoroscopy-guided fistuloplasty, c. To compare technical success in patients with arteriovenous access flow dysfunction receiving ultrasound-guided fistuloplasty versus fluoroscopy-guided fistuloplasty, and d. To compare complication rates in patients with arteriovenous access flow dysfunction receiving ultrasound-guided fistuloplasty versus fluoroscopy-guided fistuloplasty.
Study endpoints/outcomes	(a) Patency of arteriovenous fistula over a period of six months post fistuloplasty; (b) Resolution of symptoms; (c) Technical success; (d) Percentage increase in volume flow.
Sample Size	54 subjects.
Study Duration	1 July 2023 - 31 December 2024.

1.Background and Significance

Arteriovenous fistulas (AVF) are the vascular access of choice for hemodialysis patients. In the United States from August 2010 to August 2013, arteriovenous fistula (AVF) use increased from 63% to 68% and across 20 other countries in 2013, arteriovenous fistula (AVF) use ranged from 49% to 92%.[1] Patency and functionality of haemodialysis access influences survival and quality of life for patients with chronic renal failure. Progressive narrowing of the perianastomotic lumen or a more proximal part of venous circulation as a result of intimal proliferation is the main cause of failure of arteriovenous fistula. The use of Doppler sonography allows identification of more than 50% arteriovenous fistula stenosis, with 92% sensitivity and 84% specificity.[2] Percutaneous transluminal fistuloplasty is a well-established therapeutic option for patients with haemodialysis vascular access stenosis. It is conventionally guided and monitored radiographically, but this carries the risks of ionizing radiation exposure and of adverse reaction to contrast media and this is the usual practice in Hospital Kuala Lumpur and University Malay Medical Centre.

Recently, we have observed an increasing role of ultrasonography (USG) in imaging of arteriovenous fistula. Superficial location of arteriovenous fistula allows for simple and reliable visualization of vessels, guidewire, catheter, balloon, etc., with significant technical advantages including the ability to directly visualize puncture sites, stenosis, thrombus, spasm, and extravascular flow in real time. Recent studies showed that percutaneous transluminal fistuloplasty can be performed under only sonographic guidance without using a fluoroscopic machine and it is as effective as conventional percutaneous transluminal fistuloplasty as shown in Appendix 1. Since more than a decade of described ultrasound-guided fistuloplasty, many small series have been published till date, but most of them studied small number population and without direct head-to-head comparison with fluoroscopy-guided fistuloplasty as shown in Appendix 2. To overcome these limitations and further evaluate the efficacy of the procedure, we would like to compare patency of arteriovenous access flow dysfunction post ultrasound-guided fistuloplasty versus fluoroscopy-guided fistuloplasty.

We would like to research upon the efficacy of ultrasound-guided fistuloplasty as an alternative to fluoroscopy-guided fistuloplasty to prolong patency of patients with arteriovenous access flow dysfunction.

2. Objective

To determine the efficacy of ultrasound-guided fistuloplasty compared to fluoroscopy-guided fistuloplasty in patients with arteriovenous access flow dysfunction.

3. Methodology

Study design: Multicentre, randomized controlled trial.
Location: Hospital Kuala Lumpur and University Malaya Medical Centre.
Population: Vascular clinic patients in Kuala Lumpur Hospital and University Malaya Medical Centre.

1. Treatment group: Patients who underwent ultrasound-guided fistuloplasty for arteriovenous access flow dysfuntion are assessed prospectively for a period of 6 months.
2. Control group: Patients who underwent fluoroscopy-guided fistuloplasty for arteriovenous access flow dysfuntion are assessed prospectively for a period of 6 months.

Sampling method: Simple random sampling.

3.1 Study Type and Design

This is an experimental study employing a prospective randomized controlled trial.

The primary outcome would be to compare the patency of arteriovenous fistula at one, three and six months.
Secondary outcomes shall include:

- To capture data regarding variables that may affect patency of arteriovenous access flow dysfunction post ultrasound-guided fistuloplasty versus fluoroscopy-guided fistuloplasty,
- To compare technical success (defined as clinical palpable thrill, radiographic finding of less than 30% recoil and ultrasonographic finding of continuous segment of dilated vein to 5-6mm and continuous flow rate of more than 500ml/min) in patients with arteriovenous access flow dysfunction receiving ultrasound-guided fistuloplasty versus fluoroscopy-guided fistuloplasty and
- To compare complication rates in patients with arteriovenous access flow dysfunction receiving ultrasound-guided fistuloplasty versus fluoroscopy-guided fistuloplasty

Patients are randomized using simple randomization method. Treatment plans are divided equally between ultrasound-guided fistuloplasty and fluoroscopy-guided fistuloplasty. An application “sealedenvelope.com” is used for this purpose. The application does this via a built in random number generator.

After assessing for eligibility, patients will be radomized equally with a ratio 1:1 to ultrasound-guided fistuloplasty group and fluoroscopy-guided fistuloplasty group.

Both interventions will be done in operation theatre to maintain sterility. After cleaning and draping the area of interest, local anaesthesia is given to the puncture site. A puncture needle is used to gain access to the arteriovenous fistula followed by a guide wire. Then, a sheath with an appropriate size is placed and a balloon catheter of adequate size is inserted over the guide wire and inflated for 2 minutes. Ultrasound is used in the subject group to monitor technical success. On table visualization of continuous segment of dilated vein to 5-6mm and continuous flow rate of more than 500ml/min signifies the end points of the procedure. Fluoroscopy is used in the control group to assess for technical success. On table fistulogram visualization of less than 30% recoil of the target lesion signifies technical success. After a satisfactory result, a figure of 8 suture is placed with manual inflow occlusion. Post procedure, patients will be observed for any signs of haematoma or bleeding. If there are no immediate complications, patients will be discharged on the same day.

These procedures will be performed either by vascular surgeons or interventional radiologists below tabled:

OPERATOR	FISTULOPLASTY		CENTRE	DESIGNATION
	ULTRASOUND-GUIDED	FLUOROSCOPY-GUIDED		
Mr Ahmad Rafizi Hariz Ramli	√		University Malaya Medical Centre	Vascular surgeon
TBD		√	University Malaya Medical Centre	Interventional radiologist
Mr Putera Mas Pian	√	√	Hospital Kuala Lumpur	Vascular surgeon

Cases with serious complications such as extravascular leak or significant pseudoaneurysm will be admitted for monitoring. If the complications are resolved then, the patient will be discharged. Follow-up may be scheduled earlier.

Follow-up will be done at two weeks, one month, three months and six months. Assessment during follow-up includes:

- Resolution of symptoms (prolonged post dialysis bleeding or difficult access cannulation).
- Reduction of venous dialysis pressure to below predefined threshold values. (the acceptable value is less than 150mmHg)
- Measurement of the volume flow (the acceptable value is more than 500ml/min), flow characteristics (the acceptable characteristic is laminar flow) and diameter of the target lesion (the acceptable diameter is between 5-6mm) using duplex ultrasound.

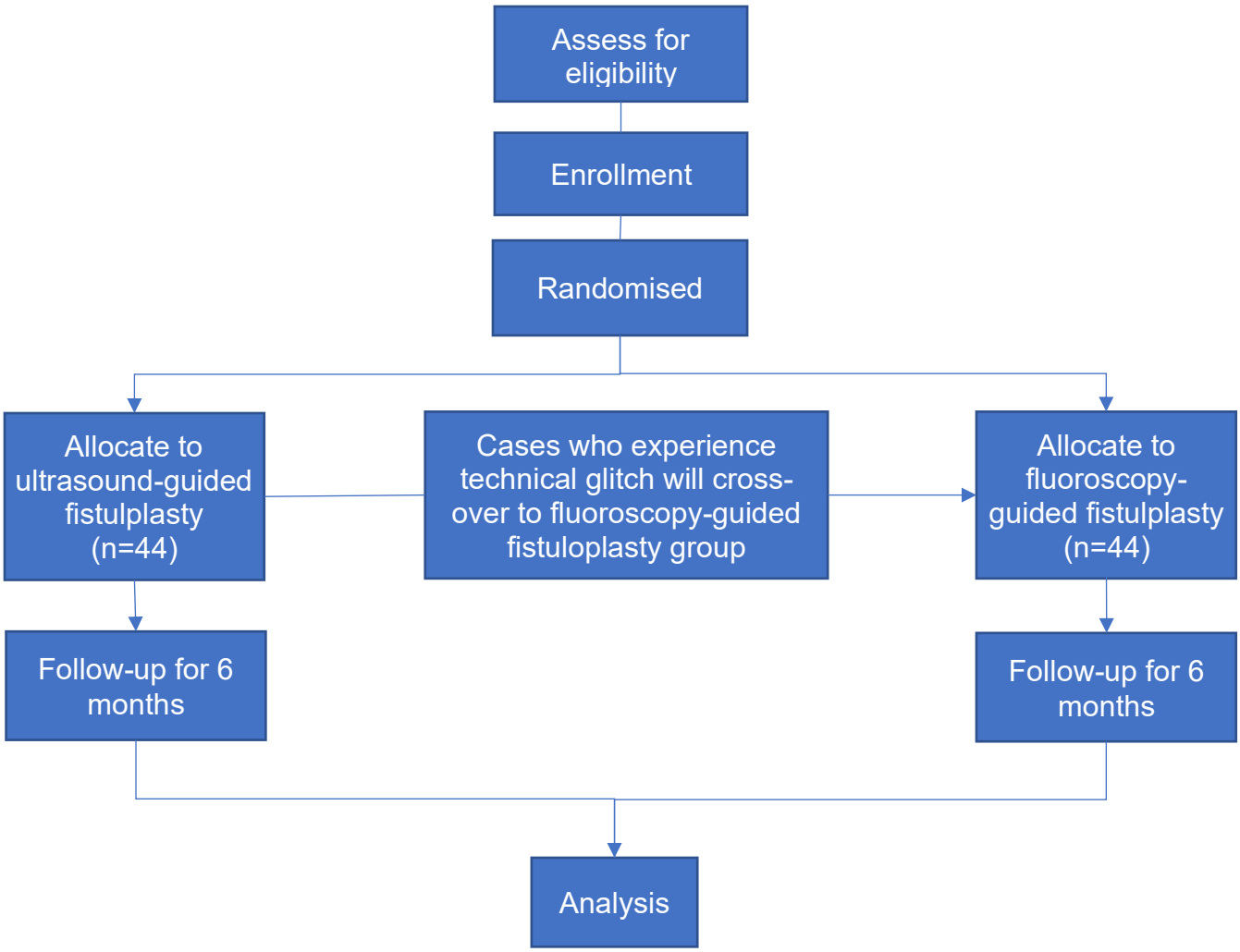
In the event of a negative outcome during the first post fistuloplasty follow-up, it will be determined whether it is due to:

- a missed stenotic segment invisible to ultrasound or
- it is a case of severe stenotic segment refractory to fistuloplasty.

Patients belonging to the former category will cross-over to the fluoroscopic-guided fistuloplasty group. In the latter case, there is no reason to repeat the fistuloplasty regardless of the imaging method (ultrasound or fluoroscopy). Ideally, these particular patients should receive drug-coated balloon (DCB) fistuloplasty which is beyond the scope of this study. There is no alternative apart from switching to fluoroscopic-guided fistuloplasty.

Although patients on anticoagulants are excluded from this study, subjects may well be prescribed anticoagulants should they consult family doctors. As a precaution, a paragraph in the patient information sheet (PIS) clearly advised patients against consuming anticoagulants.

Consort Flowchart



3.2 Study Population

All adult patients with arteriovenous access flow dysfunction in Hospital Kuala Lumpur and University Malaya Medical Centre during the period 1 July 2023 – 30 June 2024.

3.3 Inclusion Criteria

NO.	INCLUSION CRITERIA	EVALUATION METHOD.
1	Patient able to comprehend English or Malay language.	Speak to patient.
2	Patient aged ⩾18 years and ⩽80 years.	Examine patient personal data.
3	Patient is willing to comply with protocol.	Ask the patient.
4	Native AVF that is able to provide prescribed dialysis consistently with 2 needles for >2/3 of dialysis sessions within 4 consecutive weeks.	Ask the patient & examine dialysis record.
5	Patient has a reasonable expectation of remaining on haemodialysis for 6 months.	Ask the patient.

6	Dampened thrill or pulsatile flow.	Palpate the arteriovenous fistula.
7	Volume flow (VF) <500 ml/min.	Ultrasound doppler measurement.
8	Severe stenosis (>50%) of arteriovenous (AV) access measured on color image and confirmed by peak systolic velocity (PSV) ratio of ≥3 in the inflow artery, anastomosis, or in the outflow vein.	Ultrasound doppler measurement.

3.4 Exclusion Criteria

NO.	EXCLUSION CRITERIA	EVALUATION METHOD.
1	Prior history of fistuloplasty.	Ask the patient and examine hospital record.
2	Thrombosed or completely occluded fistula or outflow vein.	Palpate the arteriovenous fistula and by using ultrasound doppler.
3	Non-mature AVF.	Palpate the arteriovenous fistula and by using ultrasound doppler.
4	Arteriovenous grafts.	Ask the patient, examine hospital record and by using ultrasound doppler.
5	Suspected central vein stenosis/ cephalic arch stenosis - arm edema or Doppler detected suspicion of the same.	Ultrasound doppler measurement
6	Non consenting patient.	Ask the patient
7	Metastatic cancer or terminal medical condition.	Ask the patient and examine hospital record.
8	Limited life expectancy (<6 months).	Ask the patient and examine hospital record.
9	Blood coagulation disorders (haemophilia/ Von Willebrand disease/ clotting factor deficiencies/ liver disease).	Ask the patient and examine hospital record.
10	Connective tissue disease (rheumatoid arthritis/ lupus).	Ask the patient and examine hospital record.
11	Sepsis or active infection.	Ask the patient and examine for any signs of infection.
12	Planned access abandonment within 6 months (eg, peritoneal dialysis or transplant).	Ask the patient.
13	Pregnant women or women of childbearing potential who are not following an effective method of contraception.	Ask the patient and obtain urine pregnancy test.
14	Allergy or other known contraindication to iodinated media contrast.	Ask the patient and examine hospital record.
15	Patient enrolled in another access maintenance trial.	Ask the patient.

3.5 Withdrawal Criteria
Subjects can choose to withdraw at any time. Subjects may be withdrawn if the investigator deems that it is detrimental or risky for the subject to continue. All withdrawn subjects should attend the final study visit. Withdrawn subjects will not be replaced.

3.6 Sample Size
Based on a power of 80% (β=0.2), alpha of 0.05, a response anticipated difference of 90% in ultrasound-guided fistuloplasty group and 52.4% in fluoroscopy-guided fistuloplasty group, the calculated sample size for each group is 22 patients. Allowing for 20% dropout, a final sample size of 27 per group will be used.

3.7 Study Duration and Timeline
- Stage 1, data collection and data analysis - 8-12 months.
- Stage 2, follow-up - 6 months.
- Stage 3, presentation and publication - 6-12 months.

The participation duration for each subject is 6 months.

3.8 Study Visits and Procedures
Follow-up will be done at two weeks, one month, three months and six months.
Assessment during follow-up includes:
- Resolution of symptoms (prolonged post dialysis bleeding or difficult access cannulation).
- Reduction of venous dialysis pressure to below predefined threshold values. (the acceptable value is less than 150mmHg)
- Measurement of the volume flow (the acceptable value is more than 500ml/min), flow characteristics (the acceptable characteristic is laminar flow) and diameter of the target lesion (the acceptable diameter is between 5-6mm) using duplex ultrasound.

3.9 Statistical Analysis Plan
The data analysis will be done using the SPSS version 26.0 Descriptive date will be expressed as mean ± standard deviation (SD) for numerical data and frequency (percentage) for categorical data. Independent t-test will be used to analyse the primary objective. Secondary objective will be analyzed using logistic regression. A value of $P < 0.05$ is considered statistically significant. The data collected will be analyzed using an per protocol basis.

3.10 Risk and benefit to study participants
As stated in the literature above, there are no serious side effects known to be caused by the investigational procedure. The study procedures are all routine procedures for the disease/condition studied. There is thus minimal risk for subjects.

This study may avoid radiation hazard and eliminates contrast-related hazards in already renal compromised patient. The equipment required is readily available. It can be accomplished in daycare setting, thus reducing the burden on theaters or catheter laboratories. It is instrumental in achieving rapid turnover with decreased in-hospital duration for patients.

3.11 Risk Benefit Assessment

As stated above, there is minimal risk from the investigational study procedures. Study findings shall avoid radiation hazard and eliminates contrast-related hazards in already renal compromised patient. The expected benefit outweighs the minimal risk to subjects and thus this study should be supported. If any injuries do occur as a direct result of participating in the study, treatment for such injuries shall be provided.

Leskovar et al.[3] reported 93% technical success with minor complications that were self-limiting and can be managed successfully by direct pressure. Complications include:

1. venous rupture (3.5%),
2. post-procedural thrombosis (1%),
3. balloon rupture with conversion to surgical procedure (0.5%),
4. guide wire false route (0.5%), and
5. pseudo-aneurysm at puncture site (0.5%).

Given that the intervention procedure is the exact same technique, as long as a minimum image quality is available, the outcome would essentially be the same for either imaging techniques. Complications arising from image quality would no longer matter.

In the case of **venous rupture**: tiny venous rupture of pseudoaneurysm can be managed by direct hand compression for 20 minutes and balloon occlusion or by placing covered stent. Extravascular leak or significant pseudyaneurysm require emergency surgical repair.

Cases of **acute thrombotic occlusion** at access and plasty site can be managed successfully by giving additional heparin, thromboaspiration and over-the-wire Fogarty catheter.

Difficulty in recovering **ruptured balloon** requires either surgical removal or using ultrasound-guided snare.

We provide a comparison between the two visual modalities of fistuloplasty, as reported by Cho et al.[4] in the table below.

NO.	COMPLICATIONS	FISTULOPLASTY		MITIGATION
		ULTRASOUND-GUIDED	FLUOROSCOPY GUIDED	
1	Vessel rupture	2/53 (3.8%)	1/90 (2.2%)	Successfully managed by balloon tamponade technique
2	Access thrombosis	1/53 (1.9%)	1/90 (2.2%)	-
3	Aneurysm development	-	1/90 (2.2%)	-
4	Sheath haematoma	-	1/90 (2.2%)	-

3.12 Ethics of Study

The study will be conducted in compliance with ethical principles outlined in the Declaration of Helsinki and Malaysian Good Clinical Practice Guideline

Potentially vulnerable subjects (for example, pregnant and lactating women, children, prisoners, cognitively impaired and critically ill subjects) will be excluded from the study.

3.13 Informed Consent/Assent Process

Patients shall be informed of the study during their usual clinic visits. If they are interested, they will be briefed on it and given a copy of the Patient information sheet to read. If need be, they can take it home where they will be able to read through it properly and at leisure. No time limit is imposed. Once a patient agrees, an appointment will be made for him/her to meet with the principal investigator during which time the patient will again be briefed and given the opportunity to ask questions and to be clear about any remaining doubt. Given the patients willingness, the consent form will then be duly filled, signed and dated.

3.14 Privacy and Confidentiality

All information obtained in this study are subject to all applicable data security and confidentiality laws of Malaysia. As such, they will be treated in a manner respecting this fact. Your identity will thus be protected.

Raw data will be entered in hard copy data collection form. These will be kept safe at “Unit Rekod” of Hospital Kuala Lumpur and University Malaya Medical Centre.

The same data will be entered in a password-protected excel file in the Principal Investigator’s computer for the purpose of analysis. Identification numbers instead of patient identifiers will be used on subject data sheets. Upon completion of the study, soft copies of the data will be kept on CDs and erased from computer hard drives. Both soft and hardcopies of the data will be archived in the respective hospital record offices for a minimum of seven years after which, they will be destroyed.

Subjects will not be allowed to view their personal study data. Subjects can write to the investigators to request access to study findings.

3.15 Conflict of Interest

The investigators declare they have no conflict of interest.

3.16 Publication Policy

No personal information will be disclosed and subjects will not be identified when the findings of the survey are published.

3.17 Termination of Study

Subjects will be informed if the study is terminated and follow-up visits will be arranged if needed.

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Appendix 1				
Study details		**Primary patency (%)**		
Investigators	Intervention or comparison	1-month	3-month	6-month
Ghanwat et al.,[5] 2021	USG-guided fistuloplasty	100	88.1	77.6
Wakabayashi et al.,[6] 2013	USG-guided fistuloplasty	94.4	-	-
Gorin et al.,[7] 2011	USG-guided fistuloplasty	93	93	
Ascher et al.,[8] 2009	USG-guided fistuloplasty	96	76	53
Marks et al.,[9] 2008	USG-guided fistuloplasty	-	90	90
Marks et al.,[10] 2008	USG-guided fistuloplasty	100	100	90
Bacchini et al.,[11] 2000	USG-guided fistuloplasty	100	-	-
Karmota et al.,[12] 2020	Fluoroscopy-guided fistuloplasty	-	100	90

Appendix 2				
Investigators	**Study type**	**Intervention or comparison**	**n**	**Technical success**
Ghanwat et al.,[5] 2021	Prospective cohort study	USG-guided fistuloplasty	67	100%
Leskovar et al.,[3] 2017	Prospective cohort study	USG-guided fistuloplasty	228	93%
Banerjee et al.,[13] 2017	Prospective cohort study	USG-guided fistuloplasty	43	36/43 (84%)

Appendix 2				
Investigators	**Study type**	**Intervention or comparison**	**n**	**Technical success**
Cho et al.,[4] 2017	Case control study	USG-guided fistuloplasty vs conventional fistuloplasty	143	UG-PTA: 51/53 (96.2%); C-PTA: 84/90 (93.3%)
Wakabayashi et al.,[6] 2013	Prospective cohort study	USG-guided fistuloplasty	2342	4288/4414 (97.1%)
Fox et al.,[14] 2011	Prospective cohort study	USG-guided fistuloplasty	223	219/223 (98.2%)
Gorin et al.,[7] 2011	Case control study	USG-guided fistuloplasty	31	-
Ascher et al.,[8] 2009	Prospective cohort study	USG-guided fistuloplasty	32	-
Marks et al.,[9] 2008	Prospective cohort study	USG-guided fistuloplasty	20	-
Kim et al.,[15] 2007	Prospective cohort study	USG-guided fistuloplasty	45	10/10 (100%)
Marks et al.,[10] 2007	Prospective cohort study	USG-guided fistuloplasty	10	100%
Bacchini et al.,[11] 2000	Prospective cohort study	USG-guided fistuloplasty	12	12/12 (100%)
Wittenberg et al.,[16] 1996	Prospective cohort study	USG-guided fistuloplasty	39	38/39 (97%)