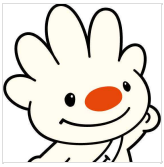

Version 3

May 20, 2021

Efficacy and safety of endovascular arteriovenous fistula creation with comparison to surgically created fistulas: a systematic review and meta-analysis protocol V.3

Yoshinosuke Shimamura[1], Yasutaka Kuniyoshi[2], Hajime Yamazaki[3], Yasushi Tsujimoto[4,5]

[1]Department of Nephrology, Teine Keijinkai Medical Center, Sapporo, Hokkaido, Japan;

[2]Department of Pediatrics, Tsugaruhoken Medical COOP Kensei Hospital, Hirosaki, Japan;

[3]Section of Clinical Epidemiology, Department of Community Medicine, Graduate School of Medicine, Kyoto University, Kyoto, Japan;

[4]Systematic Review Workshop Peer Support Group (SRWS-PSG), Osaka, Japan;

[5]Department of Nephrology and Dialysis, Kyoritsu Hospital, Kawanishi, Hyogo, Japan

dx.doi.org/10.17504/protocols.io.bu3tnynn

Shimamura Y

Yoshinosuke Shimamura
Teine Keijinkai Medical Center

ABSTRACT

This systemic review and meta-analysis aimed to evaluated existing evidence on the clinical efficacy and safety of endovascular arteriovenous fistula creation by directly comparing it with surgical arteriovenous fistula creation among patients with chronic kidney disease requiring hemodialysis.

DOI

dx.doi.org/10.17504/protocols.io.bu3tnynn

PROTOCOL CITATION

Yoshinosuke Shimamura, Yasutaka Kuniyoshi, Hajime Yamazaki, Yasushi Tsujimoto 2021. Efficacy and safety of endovascular arteriovenous fistula creation with comparison to surgically created fistulas: a systematic review and meta-analysis protocol. **protocols.io**
https://dx.doi.org/10.17504/protocols.io.bu3tnynn
Version created by Yoshinosuke Shimamura

KEYWORDS

chronic kidney disease, hemodialysis, endovascular arteriovenous fistula, Ellipsys, everlinQ, Meta-analysis

CREATED

May 17, 2021

LAST MODIFIED

May 20, 2021

PROTOCOL INTEGER ID

50003

GUIDELINES

Lock CE et al. KDOQI clinical practice guideline for vascular access: 2019 update. Am J Kidney Dis. 2020;75:S1-S164.

MATERIALS TEXT

References

1. Shamseer L, Moher D, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *BMJ*. 2015;349(jan02 1):g7647-g7647. doi:10.1136/bmj.g7647
2. Sterne JAC, Savović J, Page MJ, et al. RoB 2: a revised tool for assessing the risk of bias in randomized trials. *BMJ*. August 2019:l4898. doi:10.1136/bmj.l4898
3. Higgins JPT, Thomas J, Chandler J, et al. Cochrane Handbook for Systematic Reviews of Interventions version 6.0 (updated July 2019). Cochrane, 2019.
4. Furukawa T a, Barbui C, Cipriani A, Brambilla P, Watanabe N. Imputing missing standard deviations in meta-analyses can provide accurate results. *J Clin Epidemiol*. 2006;59(1):7-10. doi:10.1016/j.jclinepi.2005.06.006
5. Higgins JP, White IR, Wood AM. Imputation methods for missing outcome data in meta-analysis of clinical trials. *Clin Trials J Soc Clin Trials*. 2008;5(3):225-239. doi:10.1177/1740774508091600
6. Guyatt G, Oxman AD, Akl E a, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. *J Clin Epidemiol*. 2011;64(4):383-394. doi:10.1016/j.jclinepi.2010.04.026
7. Zhang J, Yu KF. What's the relative risk? A method of correcting the odds ratio in cohort studies of common outcomes. J Am Med Assoc. 1998;280(19):1690–1.

Citation: Yoshinosuke Shimamura, Yasutaka Kuniyoshi, Hajime Yamazaki, Yasushi Tsujimoto (05/20/2021). Efficacy and safety of endovascular arteriovenous fistula creation with comparison to surgically created fistulas: a systematic review and meta-analysis protocol. https://dx.doi.org/10.17504/protocols.io.bu3tnynn

A	B
#1	Kidney Diseases[mh]
#2	Renal Dialysis[mh]
#3	ESRD[tiab]
#4	end stage renal disease[tiab]
#5	ESKD[tiab]
#6	end stage kidney disease[tiab]
#7	CKD[tiab]
#8	chronic kidney disease[tiab]
#9	chronic renal failure[tiab]
#10	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9
#11	Arteriovenous Shunt, Surgical[mh]
#12	Endovascular Procedures[mh]
#13	#11 AND #12
#14	intravascular procedures[tiab]
#15	intravascular techniques[tiab]
#16	percutaneous arteriovenous fistula[tiab]
#17	Ellipsys[tiab]
#18	everlin Q[tiab]
#19	hemodialysis shunt[tiab]
#20	#13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19
#21	#10 AND #20

Appendix 1: MEDLINE (PubMed) search strategy

Citation: Yoshinosuke Shimamura, Yasutaka Kuniyoshi, Hajime Yamazaki, Yasushi Tsujimoto (05/20/2021). Efficacy and safety of endovascular arteriovenous fistula creation with comparison to surgically created fistulas: a systematic review and meta-analysis protocol. https://dx.doi.org/10.17504/protocols.io.bu3tnynn

A	B
#1	[mh "Renal Dialysis"]
#2	[mh "Kidney Diseases"]
#3	ESRD:ti,ab
#4	"end stage renal disease":ti,ab
#5	ESKD:ti,ab
#6	"end stage kidney disease":ti,ab
#7	CKD:ti,ab
#8	"chronic kidney disease":ti,ab
#9	"chronic renal failure":ti,ab
#10	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9
#11	[mh "Arteriovenous Shunt, Surgical"]
#12	[mh "Endovascular Procedures"]
#13	#11 AND #12
#14	"intravascular procedures":ti,ab
#15	"intravascular techniques":ti,ab
#16	"percutaneous arteriovenous fistula":ti,ab
#17	Ellipsys:ti,ab
#18	everlinQ:ti,ab
#19	"hemodialysis shunt":ti,ab
#20	#13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19
#21	#10 AND #20

Appendix 2: CENTRAL (Cochrane Library) search strategy

Citation: Yoshinosuke Shimamura, Yasutaka Kuniyoshi, Hajime Yamazaki, Yasushi Tsujimoto (05/20/2021). Efficacy and safety of endovascular arteriovenous fistula creation with comparison to surgically created fistulas: a systematic review and meta-analysis protocol. https://dx.doi.org/10.17504/protocols.io.bu3tnynn

A	B
S1	"EMB.EXACT.EXPLODE("kidney disease")
S2	"EMB.EXACT.EXPLODE("hemodialysis")
S3	ab(ESRD) OR ti(ESRD)
S4	ab(end stage renal disease) OR ti(end stage renal disease)
S5	ab(ESKD) OR ti(ESKD)
S6	ab(end stage kidney disease) OR ti(end stage kidney disease)
S7	ab(CKD) OR ti(CKD)
S8	ab(chronic kidney disease) OR ti(chronic kidney disease)
S9	ab(chronic renal failure) OR ti(chronic renal failure)
S10	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9
S11	"EMB.EXACT.EXPLODE("arteriovenous shunt")
S12	"EMB.EXACT.EXPLODE("endovascular surgery")
S13	S11 AND S12
S14	ab(intravascular procedures) OR ti(intravascular procedures)
S15	ab(intravascular techniques) OR ti(intravascular techniques)
S16	ab(percutaneous arteriovenous fistula) OR ti(percutaneous arteriovenous fistula)
S17	ab(Ellipsys) OR ti(Ellipsys)
S18	ab(everlin Q) OR ti(everlin Q)
S19	ab(hemodialysis shunt) OR ti(hemodialysis shunt)
S20	S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19
S21	S10 AND S20

Appendix 3: EMBASE (Dialog) search strategy

Appendix 4: ICTRP search strategy

#1 Conditions: (Chronic Kidney Diseases, Renal Dialysis)
#2 Intervention: (percutaneous arteriovenous fistula, Ellipsys, everlinQ)
#3 #1 AND #2
Recruitment status is ALL.

Appendix 5: ClinicalTrials.gov search strategy.

Condition or disease: Renal Dialysis AND Chronic Kidney Disease
Intervention: percutaneous arteriovenous fistula

Citation: Yoshinosuke Shimamura, Yasutaka Kuniyoshi, Hajime Yamazaki, Yasushi Tsujimoto (05/20/2021). Efficacy and safety of endovascular arteriovenous fistula creation with comparison to surgically created fistulas: a systematic review and meta-analysis protocol. https://dx.doi.org/10.17504/protocols.io.bu3tnynn

SAFETY WARNINGS

None.

DISCLAIMER:

Author contributions:
YS is the guarantor. YS, HY, YK, and YT drafted the manuscript.
All authors contributed to the development of the selection criteria, the risk of bias assessment strategy and data extraction criteria. YS, HY, YK, and YT developed the search strategy. HY, YK, and YT provided statistical expertise.All authors read, provided feedback and approved the final manuscript.

Introduction

1 Functional vascular access is the lifeline of hemodialysis patients. The Kidney Disease Outcomes Quality Initiative guideline strongly recommends the creation of arteriovenous fistulas for long-term vascular access. Although arteriovenous fistulas have been created using open surgery, endovascular techniques, the Ellipsys Vascular Access System (Avenu Medical, San Juan Capistrano, California) and the everlinQ endovascular arteriovenous fistula system (TVA Medical, Austin, Texas), were approved by the Food and Drug Administration in 2018.
A recent meta-analysis of the endovascular devices reported that the 90-day maturation rate and procedure-related complication rate were 97.5 % and 5.46 %, respectively. Despite the comprehensive search, this meta-analysis did not consider patient-centered outcomes such as patient satisfaction, and it did not directly compare endovascular techniques and surgical arteriovenous creation. To the best of our knowledge, there have been no reviews directly comparing endovascular arteriovenous fistula creation and surgical arteriovenous fistula creation to investigate clinically relevant outcomes, including vascular access maturation, complications, and patient satisfaction.
This systematic review and meta-analysis aimed to critically evaluate existing evidence on the clinical efficacy and safety of endovascular arteriovenous fistula creation for the management of chronic kidney disease requiring hemodialysis.

Citation: Yoshinosuke Shimamura, Yasutaka Kuniyoshi, Hajime Yamazaki, Yasushi Tsujimoto (05/20/2021). Efficacy and safety of endovascular arteriovenous fistula creation with comparison to surgically created fistulas: a systematic review and meta-analysis protocol. https://dx.doi.org/10.17504/protocols.io.bu3tnynn

Research question

2 P: Patients with chronic kidney disease
I: Endovascular arteriovenous fistula creation
C: Surgical arteriovenous fistula creation
O: Maturation of fistula, Procedure-related complications, Patient satisfaction

The research question addressed in this study is: "Does endovascular arteriovenous fistula creation have better efficacy and safety, including maturation of fistula, procedure-related complications, and patient satisfaction, compared with surgical arteriovenous fistula creation among patients with chronic kidney disease.

Method

3

3.1 Protocol

We used a systematic review protocol template (dx.doi.org/10.17504/protocols.io.biqrkdv6). We followed the Preferred reporting items for systematic review and meta-analysis 2020 (PRISMA-2020) for preparing this protocol.[1] We will publish this protocol in protocols.io (https://www.protocols.io/).

3.2 Inclusion criteria of the articles for the review

3.2.1 Type of studies

We will include randomized controlled, cluster-randomized, quasi-randomized, non-randomized trials, and observational studies that assess theefficacy and safety of endovascular arteriovenous fistula creation. We will not apply language or country restrictions. We will include all papers including published, unpublished articles, abstract of conference, and letter.
We will exclude case reports, case series, animal and laboratory studies, and literature reviews. We will not exclude studies based on the observation period or publication year.

3.2.2 Study participants

Studies will be included regardless of the etiology of chronic kidney disease, follow-up duration, and country of origin. We will include patients of any age, sex, and race, but exclude those with treatment for dysfunctional hemodialysis arteriovenous fistulas.

3.2.3 Intervention

Intervention is defined as any percutaneous endovascular approach to creating an arteriovenous fistula, including the Ellipsys Vascular Access System (Avenu Medical, San Juan Capistrano, California), the everlinQ endovascular arteriovenous fistula system (TVA Medical, Austin, Texas), and other devices. We will include studies in which the patients receive the revascularization of arteriovenous fistulas.
We will exclude studies in which the patients in the intervention group receive arteriovenous creation other than the upper extremities; however, we will not exclude studies regardless of the methods for anesthesia (general or local) and the expertise and clinical experience of operators.

3.2.4 Control

Control is defined as any surgical approach to creating an arteriovenous fistula, regardless of the methods and selections of the artery and vein for anastomosis. We will include studies in which the patients receive the placement of arteriovenous grafts or the revascularization of arteriovenous fistulas. We will exclude studies in which the patients receive surgical arteriovenous creation other than the upper extremities; however, we will not exclude studies regardless of the methods for anesthesia (general or local) and the expertise and clinical experience of operators.

3.3 Type of outcomes

Citation: Yoshinosuke Shimamura, Yasutaka Kuniyoshi, Hajime Yamazaki, Yasushi Tsujimoto (05/20/2021). Efficacy and safety of endovascular arteriovenous fistula creation with comparison to surgically created fistulas: a systematic review and meta-analysis protocol. https://dx.doi.org/10.17504/protocols.io.bu3tnynn

3.3.1 Primary outcomes

1. Maturation of fistula
Definition: Arteriovenous fistula blood flow of ≥500 ml per minute and an outflow vein diameter ≥5 mm confirmed by duplex ultrasound or similar definition.
Measurement: Incidence proportion of maturation of fistula.
Period: The longest follow-up period after arteriovenous fistula creation.

2. Procedure-related complications
Definition: Definition of adverse events is set by original authors.
Measurement: Incidence proportion of procedure-related complications.
Period: From the time of procedure initiation to completion.

3. Patient satisfaction
Definition: Definition of patient satisfaction is set by original authors.
Measurement: Measurement of patient satisfaction is set by original authors.
Period: At the completion of procedure.

3.3.2 Secondary outcomes

1. Procedural technical success
Definition: Presence of blood flow in the outflow vein(s) confirmed by duplex ultrasound.
Measurement: Incidence proportion of procedural technical success.
Period: At the completion of procedure.

2. Procedure time
Definition: From the time of procedure initiation to completion.
Measurement: Minutes.
Period: From the time of procedure initiation to completion.

3. All adverse events
Definition: Definition of adverse events is set by original authors.
Measurement: Incidence proportion of all adverse events.
Period: during the follow-up period.

4. Medical expenditure
Definition: Total medical financial cost, including hospitalization, procedure, and materials.
Measurement: Reports from medical institutions or patients (US dollar equivalent)
Period: From the time of hospital admission to hospital discharge.

3.4 Search method

3.4.1 Electronic search

We will search the following databases:
1. MEDLINE (PubMed);
2. the Cochrane Central Register of Controlled Trials (Cochrane Library);
3. EMBASE (Dialog);
See Appendix 1, 2, and 3 for the search strategies.

3.4.2 Other resources

We will also search the following databases for ongoing or unpublished trials:
1. the World Health Organization International Clinical Trials Platform Search Portal (ICTRP);
2. ClinicalTrials.gov;
See Appendix 4, 5 for the search strategies.
We will check the reference lists of studies, including international guidelines (KDOQI clinical practice guideline for vascular access: 2019 update) as well as the reference lists of eligible studies and articles citing eligible studies. We will ask the authors of original studies for unpublished or additional data.

Citation: Yoshinosuke Shimamura, Yasutaka Kuniyoshi, Hajime Yamazaki, Yasushi Tsujimoto (05/20/2021). Efficacy and safety of endovascular arteriovenous fistula creation with comparison to surgically created fistulas: a systematic review and meta-analysis protocol. https://dx.doi.org/10.17504/protocols.io.bu3tnynn

3.5 Data collection and analysis

3.5.1 Selection of the studies

Two independent reviewers (YS and HY) will screen titles and abstracts, followed by the assessment of the eligibility based on the full texts. We will contact the original authors if relevant data is missing. Disagreements between the two reviewers will be resolved by discussion, and if this fails, a third reviewer will act as an arbiter (YT or YK).

3.5.2 Data extraction and management

Two reviewers (YS and HY) will perform independent data extraction of the included studies using a standardized data collection form. We will use a pre-checked form using 10 randomly selected studies. The form will include the information on study design, study population, interventions, unadjusted and adjusted effect estimates, and outcomes. Any disagreements will be resolved by discussion, and if this fails, a third reviewer will act as an arbiter (YT or YK).

3.6 Assessment of risk of bias in included studies

Two reviewers (YS and HY) will evaluate the risk of bias independently using theROBINS-I.[2] Disagreements between the two reviewers will be discussed, and if this fails, a third reviewer (YT or YK) will be acting as an arbiter, if necessary.

3.7 Measures of treatment effects

We will pool the odds ratios and the 95% confidence intervals (CIs) for the following binary variables: Maturation of fistula, Procedure-related complications, Procedural technical success.
If adjusted ORs and 95% CIs of the outcomes are not available and if the RRs are reported in primary studies, we will use a method reported by Zhang[7]et al. to transform RRs into ORs. If only the HRs were reported, we will contact the authors to confirm the ORs and/or RRs. If ORs are not available after querying the authors, we will integrate them with ORs and HRs, respectively.
We will pool the mean differences and the 95% CIs for the following continuous variables: Patient satisfaction, Procedure time, and Medical expenditure.
If several different scales have been used in the included studies, we will pool the effect estimates using standard mean differences (SMDs)
We will summarize adverse events based on the definition by the original article, but we will not perform the meta-analysis.

3.8 Unit of analysis issues

Clustering at the level of the enrolled units in cluster randomized studies
In dealing with cluster-RCTs, for dichotomous data, we will apply the design effect and calculate effective sample size and number of events using the intra-cluster correlation coefficient (ICC) among each unit and the average cluster size, as described in Chapter 16.3.5 of the Cochrane Handbook.[3] If the ICC has not been reported, we will use the ICC of a similar study as a substitute. For continuous data, only the sample size will be reduced; means and standard deviation will remain unchanged. [3]

Multiple comparisons
All intervention groups that are relevant to this review will be included.

3.9 Handling of missing data

We will ask for not-presented data from the original authors.

3.9.1 Missing outcomes

We will analyze the data on the intention-to-treat (ITT) basis. If there is missing data that should be available but not presented in the publications, we will seek further information directly from the

Citation: Yoshinosuke Shimamura, Yasutaka Kuniyoshi, Hajime Yamazaki, Yasushi Tsujimoto (05/20/2021). Efficacy and safety of endovascular arteriovenous fistula creation with comparison to surgically created fistulas: a systematic review and meta-analysis protocol. https://dx.doi.org/10.17504/protocols.io.bu3tnynn

authors of the studies and will analyze only the available data if no additional information is forthcoming. Any imputation of the outcome data by the original investigators will be critically appraised through the risk of bias assessment.

3.9.2 Missing statistics

When original studies only report standard error or p-value for continuous outcomes, we will calculate the standard deviation based on the method by Altman.[4] If we don't know these values when we contact the authors, standard deviation will be calculated by confidence interval and t-value based on the method by Cochrane handbook[3], or validated method.[5] Validity of these methods will be analyzed by sensitivity analysis.

3.10 Assessment of heterogeneity

We will evaluate the statistical heterogeneity by visual inspection of the forest plots and calculating the I2 statistic (I2 values of 0% to 40%: might not be important; 30%to 60%: may represent moderate heterogeneity; 50% to 90%: may represent substantial heterogeneity; 75% to 100%: considerable heterogeneity). Cochrane Chi2test (Q-test) will be performed for I2 statistic, and P value less than 0.10 will be defined as statistically significant.

3.11 Assessment of reporting bias

We will search the clinical trial registry system (ClinicalTrials.gov and ICTRP) and will perform extensive literature search for unpublished trials. To assess outcome reporting bias, we will compare the outcomes defined in trial protocols with the outcomes reported in the publications. We will assess the potential publication bias by visual inspection of the funnel plot. We will conduct Egger test to assess the publication bias. We will not conduct the test when we find less than 10 trials or trials that have similar sample sizes. We will also assess the potential publication bias by visual inspection of the funnel plot.

3.12 Meta-analysis

Meta-analysis will be performed using Review Manager software (RevMan 5.4.2). We will use a random-effects model. We will prioritize the adjusted effect estimates if we extract data from observational studies.

3.13 Subgroup analysis

To elucidate the influence of effect modifiers on results, we will evaluate the subgroup analyses of the primary outcomes on the following factors when sufficient data are available.
1. Patients with diabetic nephropathy versus those with non-diabetic nephropathy.
2. Ellipsys Vascular Access System versus everlinQ endovascular arteriovenous fistula system.
3. Surgical arteriovenous fistula using native arteries and veins versus surgical placement of arteriovenous grafts.
4. Randomized clinical trials versus non-randomized studies.
5. Patients who received the first arteriovenous fistula creation versus patients who received the revascularization of arteriovenous fistulas.

3.14 Sensitivity analysis

We will undertake the following sensitivity analyses for the primary outcomes to assess whether the results of the review are robust to the decisions made during the review process.
1. Exclusion of studies using imputed statistics.
2. Inclusion of studies with complete case data

Summary of findings table

4 Two reviewers (YS and YT) will evaluate the certainty of evidence based on the GRADE (Grading of Recommendations

Citation: Yoshinosuke Shimamura, Yasutaka Kuniyoshi, Hajime Yamazaki, Yasushi Tsujimoto (05/20/2021). Efficacy and safety of endovascular arteriovenous fistula creation with comparison to surgically created fistulas: a systematic review and meta-analysis protocol. https://dx.doi.org/10.17504/protocols.io.bu3tnynn

Assessment, Development, and Evaluation) approach.[6]Disagreements between the two reviewers will be discussed, and if this fails, a third reviewer (YK) will be acting as an arbiter, if necessary.

Summary of findings table will be made for the following outcome based on the Cochrane handbook.[3]

1. Maturation of fistula
2. Procedure-related complications
3. Patient satisfaction
4. Procedural technical success
5. Procedure time

Conflict of Interest

5 The authors declare no conflicts of interest.

Support

6 Self-funding.

Citation: Yoshinosuke Shimamura, Yasutaka Kuniyoshi, Hajime Yamazaki, Yasushi Tsujimoto (05/20/2021). Efficacy and safety of endovascular arteriovenous fistula creation with comparison to surgically created fistulas: a systematic review and meta-analysis protocol. https://dx.doi.org/10.17504/protocols.io.bu3tnynn