STUDY TITLE:

RANDOMIZED TRIAL COMPARING DUAL PERCLOSE VS SINGLE ANGIOSEAL AND PERCLOSE IN PATIENTS UNDERGOING TRANSFEMORAL TAVR

"TAVI-CLOSE"

Protocol IRB #: 024-458

PROTOCOL HISTORY

Date:	**12/13/24**
Version:	**1.3**
Principal Investigator:	**Imran Baig, MD**
Sub-Investigator(s):	**Karim Al-Azizi, MD**
Statistician:	**Tsung-Wei Ma, PhD**

PROTOCOL SIGNATURE PAGE

Study Title:

Randomized trial comparing dual Perclose vs single Angioseal and Perclose in patients undergoing transfemoral TAVR

TAVI-CLOSE

Protocol Number: N/A

IRB Number: 024-458

I have read this protocol and agree to adhere to the requirements outlined within. I will provide copies of this protocol and all pertinent information to the study personnel under my supervision. I will review and discuss this material with them and ensure they are fully informed regarding the requirements of this protocol. I will also ensure that this study is conducted in compliance with this protocol, Good Clinical Practice (GCP), and all applicable regulatory agencies and their requirements.

Principal Investigator (Printed Name)

Principal Investigator (Signature) Date

STUDY TEAM CONTACT INFORMATION

Name	Contact Information	Role on Study
Imran Baig, MD	Imran.Baig@BSWHealth.org	Primary Investigator
Karim Al Azizi, MD	Karim.AlAzizi@BSWHealth.org	Sub-Investigator
Tsung-Wei Ma, PhD	TsungWei.Ma@BSWHealth.org	Statistician
Sarah Hale	Sarah.Hale@BSWHealth.org	Research Manager
Cody Dorton, DO	Cody.Dorton@BSWHealth.org	Research Fellow
Kyle McCullough, MD	Kyle.McCullough@BSWHealth.org	Research Fellow
Madhura Shah	MadhuraKapil.Shah@BSWHealth.org	Regulatory/ Other Research Associate
Bonnie Ostergren	Bonnie.ostergren@BSWHealth.org	Research Project Coordinator

Table of Contents

ABBREVIATIONS

Abbreviation	Term
TAVR	Transcatheter Aortic Valve Replacement
Perclose ProGlide	PP
AngioSeal	AS
Common Femoral Artery	CFA

SYNOPSIS

Summary/Rationale:	This prospective, randomized, parallel controlled, single center, open-label, non-inferiority study will evaluate the safety and potential complications of dual ProGlide vs single ProGlide and Angioseal for common femoral arteriotomy closure following TAVR.
Study Objectives:	The primary objective of this study is to evaluate the safety and potential complications of dual ProGlide versus single ProGlide and Angioseal for common femoral arteriotomy closure in TAVR.
Study Design:	Single-center, randomized, parallel controlled, open-label, single center, non-inferiority study
AoStudy Intervention(s):	Randomization of subjects undergoing femoral arteriotomy to dual ProGlide suture closure devices versus closure with combination of single ProGlide and Angioseal device.
Number of Subjects:	90
Inclusion Criteria:	A patient will be eligible for inclusion in this study if **he or she** meets **all** of the following criteria: 1. Age ≥ 18 years old 2. Planned to undergo TAVR via femoral access 3. Able to provide written informed consent
Exclusion Criteria:	A patient will be ineligible for inclusion in this study if **he or she** meets **any** of the following criteria: 1. Nonfemoral access 2. Previous repair or intervention of the common femoral artery 3. Previous pseudoaneurysm of the common femoral artery 4. Children below 18 years, prisoners, and patients who are unable to provide consent are excluded.
Sponsor:	Baylor Scott and White Research Institute
Principal Investigator:	Imran Baig, MD

Primary Study Site/Data Center:	The Heart Hospital Baylor Plano 1100 Allied Drive | 5th Floor Research Dept. Plano, Texas 75093
Duration of Study:	18-months

4. INTRODUCTION

4.1 Background

Transcatheter aortic valve replacement (TAVR) is an established treatment option for patients with severe symptomatic aortic stenosis and is routinely performed through the transfemoral access route. Percutaneous access site closure is usually achieved using two pre-deployed 6F Perclose ProGlide (PP) sutures. Recent studies have supported the use of single PP plus AngioSeal (AS) as a safe and effective method for TAVR access closure [1,2,3,4]. Bazarbashi et al, from the Cleveland clinic performed a retrospective review evaluating the utilization of single PP versus double PP devices for transfemoral aortic valve replacement access closure [1]. They reported successful arteriotomy closure with the single PP plus AS in nearly 75% of cases. For the remaining 25%, only a single PP was necessary for closure. A recent randomized study by Rheude et al. In Germany showed decreased risk of bleeding events when using a single PP plus AS, randomized comparative studies are scarce, and there is a need for validating studies to confirm results from these small series within different populations, including in the United States-(1,2,4,54).

5. STUDY OBJECTIVES

This study will examine the safety and efficacy of the single Perclose Proglide (PP) plus AngioSeal (AS) versus double PP for large bore access during TAVR. VARC-3 criteria will be utilized for vascular complications. The need for an additional closure device will be assessed.

6. STUDY DESIGN

This is a prospective, randomized, parallel controlled, open-label, single-center, non-inferiority clinical trial.

Approximately 90 patients undergoing TAVR with femoral access will be randomized in a 1:1 fashion to receive femoral access closure using either dual PP or single PP and AS for closure.

The primary end point of this study is the composite endpoint of main access-related bleeding ≥Type 2 and main access related major vascular complication. Secondary end points include periprocedural complications (such as acute vessel closure, leg embolization and perforation), procedural characteristics (total duration, fluoroscopy time, contrast volume, Length of hospital stay), and cost of hospitalization. A routine follow-up visit assessment will be performed at 30 days in the valve clinic (± 15-day window) and the assessment will include: any clinical change, re-interventions, and peripheral pulse evaluation.

7. STUDY POPULATION

The study population will consist of approximately 90 patients undergoing TAVR with femoral access.

7.1 Eligibility Criteria

7.1.1 Inclusion Criteria

A patient will be eligible for inclusion in this study if **he or she** meets **all** of the following criteria:

1. Age ≥ 18 years old
2. Planned to undergo TAVR via femoral access
3. Able to provide written informed consent prior to study participation

7.1.2 Exclusion Criteria

A patient will be ineligible for inclusion in this study if **he or she** meets **any** of the following criteria:

1. Non-femoral access
2. Previous repair or intervention of the common femoral artery
3. Previous pseudoaneurysm of the common femoral artery
4. Children below 18 years, prisoners, and patients who are unable to provide consent are excluded.
5. In another research study that has not granted permission to dual-enroll.

8. STUDY VISITS AND ACTIVITIES

8.1 Screening and Baseline

Consenting for study enrollment will follow standard procedures set by Baylor Scott & White Research Institute (BSWRI) IRB. The study team may perform consent procedures over the phone after a subject is mailed or emailed the consent form. Informed consent will include, but not be limited to, full understanding by the patient of study goals, procedures, risks, and endpoint.

Subjects must meet the inclusion criteria and have none of the exclusion criteria in order to be eligible for participation in this study.

Screening assessments will be collected through review of medical records and by interview after informed consent is signed. These screening evaluations may include:

- Complete Medical History (including history of previous vascular or endovascular procedures)
- Demographics
- Physical exam
- Vital signs
- Relevant lab values already in the medical record (including CBC, BMP, PT/INR, clotting time, etc.)
- Any and all relevant preoperative imaging studies (including echocardiogram, left or right heart catheterizations, angiograms, CT scans, MRI's, PFT's, ABI/PVR's, ultrasound images, etc.)

A subject is considered a screen-fail if they do not meet inclusion/exclusion criteria and/or withdraw before being randomized.

8.2 Enrollment

Patients will be seen and evaluated in valve clinic. Once need for TAVR has been established, subjects will be consented for this study. Subjects will be randomized using the REDCap database. Due to need for procedural intervention, clinicians will not be able to be blinded. A patient is considered enrolled when consent is obtained and they have been randomized into a cohort. If a subject does not undergo a TAVR, the subject is withdrawn for the study. Subject enrollment will continue until 90 subjects are randomized and undergo a TAVR. If more than 90 subjects are enrolled to meet this goal, a revision will be submitted to the IRB to increase enrollment.

8.3 Procedure/Study Visits

Pre-Procedure Visit

Patients requiring TAVR will be seen routinely in the THH Plano TAVR Clinic. At this time, a complete medical history is obtained including relevant medical conditions, demographics, exam findings, vitals, and relevant lab values as described above. Of note, the decision to undergo a TAVR will be made clinically prior to enrollment in this study. Data for the study will be collected for study purposes from the Electronic Health Record (EHR) only after informed consent is signed. Data collected from the EHR should be selected based on the most recent data prior to the TAVR and collected with 60 days of the procedure

Randomization

A subject will be randomized via a REDCap database prior to the routine TAVR. The study staff will communicate the randomization to the physicians on the case that will also need to be sub-investigators on the study. The randomization and communication will be documented in the research chart.

Procedure

Patients will undergo the planned TAVR procedure. The procedure will be conducted in the manner deemed most appropriate by the clinician. Upon completion of valve replacement, closure will proceed based on the study protocol. One cohort will be closed using two PP devices, and the other closed using one PP and AS. A routine post-closure angiogram will be obtained to ensure adequate hemostasis. Operative reports and postoperative notes will be obtained and reviewed to obtain and measure the primary and secondary endpoints of the study. Primary endpoint collected will be composite endpoint of main access-related bleeding ≥Type 2 and main access related major vascular complication (VARC 3 Criteria). Secondary endpoints will be periprocedural complications, acute vessel closure, embolization, and vessel perforation, procedural characteristics (duration, fluoroscopy time, contrast volume), length of hospital stay, and cost of hospitalization.

In the event of inadequate hemostasis on the post-closure angiogram, operators will proceed as is clinically indicated. Options for subsequent closure could include prolonged pressure, balloon tamponade, covered stent application, or cutdown. If any intervention beyond the prescribed closure devices is required, this will be recorded as an additional endpoint.

8.4 Follow-up

Subject management post-procedure will proceed via standard institutional protocol. Subjects will have a follow-up visit 30-days post-procedure in the valve clinic (± 10-day window).

Follow-up data documented at 30-days for research purposes will include:

1. Any clinical change
2. Any unplanned or planned re-interventions
3. Peripheral pulse evaluation

8.5 Withdrawal from Study

Subjects may voluntarily discontinue participation in the study at any time, for any reason. The Investigator also has the right to discontinue subjects from the study if he/she feels it is in the best interest of the subject.

Schedule of Events

Task/Procedure	Routine or Research	Pre-procedure	In-hospital procedure (Day 0)	Discharge (+/-5 days)	Day 30 (+/-15 days)
Pre-op procedures including imaging and blood draw	Routine	Data collection			
Pregnancy test (if applicable)	Routine	Data collection			
TAVR	Routine		Data collection		
Randomization to Single PP plus AS or Double PP	Research		X		
Single PP plus AS and Double PP	Routine		Data collection		
Angiogram	Routine		Data collection		
Clinic Visit	Routine				Data collection
Chart Review/ Data Collection	Research	X	X	X	X

KEY

+ = plus

- = minus

9. COMPENSATION

Participants will not receive any compensation for participating in this study.

10. COSTS

Participants will not incur any additional research-related costs due to study participation. Subject or their insurance company will be required to pay for all expenses related to regular care including procedure and other hospital care.

11. RISK AND BENEFITS TO PARTICIPANTS

11.1. Potential Benefits

There is no guarantee of direct benefit to the subjects who participate in this study. There is a possibility that closure with a single PP and AS device will decrease the cost of procedure. Future patients may benefit from the knowledge gained.

11.2 Potential Risks

11.2.1 Physical Risks

Possible risks a potentially increased risk of bleeding events based on treatment group, however the data to suggest an increased risk based on closure type is minimal and unconfirmed. Other risks include those common to patients undergoing a TAVR without being included in the study. These risks include femoral artery dissection, pseudoaneurysm, thrombosis, stricture, access site seroma, hematoma, infection, abscess, embolization of endovascular devices.

11.2.2 Psychosocial & Privacy Risks

Any time information is collected there is a potential for loss of confidentiality. Every effort will be made to keep participant's information confidential, however this cannot be guaranteed. Participation in research study may make participants feel uncomfortable. Participants will be informed that they may refuse to participate or stop their participation at any time without effect on future medical treatment or relationship with the treating physician.

11.2.3 Reproductive Risks

Women that are pregnant or think they may be pregnant, cannot take part in this study as the radiation involved may endanger the fetus. For women of child-bearing potential, a pregnancy test will be performed. All subjects of childbearing potential will need to have a blood serum pregnancy test which includes collecting 1-2 mL of blood. A urine pregnancy test is not as sensitive as a blood pregnancy test and a negative urine test does not completely rule out an early pregnancy in progress.

11.2.4 Adverse Event Reporting

An Adverse Event (AE) is any untoward sign, symptom or medical condition occurring at any time after the subject receives his/her procedure, even if the event is not considered to be related to the study. Since this study is collecting information on routine procedures, we are seeking a waiver from the IRB to only collect Adverse Events related to the primary and secondary endpoints listed in section 13.1 and 13.2. These vascular events would include:

- Aortic dissection or aortic rupture
- Vascular (arterial or venous) injury (perforation, rupture, dissection, stenosis, ischaemia, arterial or venous thrombosis including pulmonary embolism, arteriovenous fistula, pseudoaneurysm, haematoma, retroperitoneal haematoma, infection) or compartment syndrome resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
- Distal embolization (non-cerebral) from a vascular source resulting in death, amputation, limb or visceral ischaemia, or irreversible end-organ damage
- Unplanned endovascular or surgical intervention resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
- Closure device failure resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
- Vascular (arterial or venous) injury (perforation, rupture, dissection, stenosis, ischaemia, arterial or venous thrombosis including pulmonary embolism, arteriovenous fistula, pseudoaneurysm, haematoma, retroperitoneal haematoma, infection) not resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
- Distal embolization treated with embolectomy and/or thrombectomy, not resulting in death, amputation, limb or visceral ischaemia, or irreversible end-organ damage
- Any unplanned endovascular or surgical intervention, ultra-sound guided compression, or thrombin injection, not resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
- Closure device failure not resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment

Adverse events will be monitored and reported from the start of the study procedure until 30-days after the index procedure. Investigator or Sub-Investigator will assess all AEs/SAEs for severity and relatedness to study intervention.

A Serious Adverse Event (SAE) is an undesirable sign, symptom or medical condition which:

- is fatal
- is life threatening
- requires or prolongs hospitalization
- results in persistent or significant disability/incapacity
- constitutes a congenital anomaly or a birth defect
- is medically significant, in that it may jeopardize the subject and may require medical or surgical intervention to prevent 1 of the outcomes listed above

- Hospitalizations not necessarily considered to be SAEs are hospitalizations for:
    - treatment, which was elective or preplanned, for a pre-existing condition that did not worsen
    - treatment on an emergency, outpatient basis for an event not fulfilling any of the definitions of serious given above and not resulting in hospital admission

Only SAEs in the above listed AE categories will be collected and submitted. A death and its cause will always be collected and reported. All applicable SAEs will be followed up until resolution or permanent outcome of the event.

All AEs will be reported to IRB at the yearly continuing review of study.

SAEs and AEs will be entered on an AE log in the patient binder.

12. RISK/BENFIT ASSESSMENT

Large bore access for TAVR procedures requires percutaneous closure devices. Common practice is use of dual PP devices prior to upsizing the catheter (preclosure). Emerging data shows that use of a single PP device to decrease the size of the arteriotomy and subsequent placement of an AS collagen plug device has no difference in complication rate, and some have reported decreased rate of femoral artery stenosis. Reported risk of bleeding in second generation TAVR valve is 7.5%[6], access site infection is 2%[7], and risk of device failure is 4.4%-8.7%[8].

13. STATISTICAL METHODS

13. Statistical Methods

Kolmogorov–Smirnov tests and Q-Q plot will be used to test normality of continuous variables. For descriptive statistics, continuous variables with normal distribution will be presented as mean with standard deviation, continuous variables without normal distribution will be presented as median with first and third quartile, and categorical variables will be presented as frequencies with counts. To compare patient demographics factors, procedural characteristics, and secondary outcomes between study groups, two-sample t-test will be applied to continuous variables with normal distribution, Wilcoxon rank-sum test will be applied to continuous variables without normal distribution, and chi-square test or Fisher's exact test will be applied to categorical variables. A significant level of 5% will be utilized throughout the study unless otherwise. Unpooled Z test will be used to evaluate if success (free of primary end point) rate of one PP plus one AS is non-inferior to dual PP devices. Non-inferiority test is a one-sided test; thus 2.5% significance level will be used.

13.1 Analysis of Primary Outcome

Primary outcome of this study is a composite endpoint of main access-related bleeding and main access related major vascular complication. We will define vascular complication according to the VARC-3 criteria. This includes the following:

- Major- One of the following:
  - Aortic dissection or aortic rupture
  - Vascular (arterial or venous) injury (perforation, rupture, dissection, stenosis, ischaemia, arterial or venous thrombosis including pulmonary embolism, arteriovenous fistula, pseudoaneurysm, haematoma, retroperitoneal haematoma, infection) or compartment syndrome resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
  - Distal embolization (non-cerebral) from a vascular source resulting in death, amputation, limb or visceral ischaemia, or irreversible end-organ damage
  - Unplanned endovascular or surgical intervention resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
  - Closure device failure resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
- Minor- One of the following:
  - Vascular (arterial or venous) injury (perforation, rupture, dissection, stenosis, ischaemia, arterial or venous thrombosis including pulmonary embolism, arteriovenous fistula, pseudoaneurysm, haematoma, retroperitoneal haematoma, infection) not resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
  - Distal embolization treated with embolectomy and/or thrombectomy, not resulting in death, amputation, limb or visceral ischaemia, or irreversible end-organ damage
  - Any unplanned endovascular or surgical intervention, ultra-sound guided compression, or thrombin injection, not resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
- Closure device failure not resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
  -

13.2 Analysis of Secondary Outcomes

The following secondary outcome measures will be monitored

- Need for secondary closure device
- Periprocedural complications:
  - Acute vessel closure
  - Leg embolization
  - Vessel perforation/dissection
- Procedural characteristics

  - Total duration
  - Fluoroscopy time
  - Contrast volume
- Length of hospital stay
- Cost of hospitalization

These will be obtained primarily by chart review. Interview with patient will be used as necessary to obtain further information.

13.3 Sample Size

Un-pooled Z test is utilized to test if success (free of primary end point) rate of one Perclose ProGlide (PP) plus one AngioSeal (AS) is non-inferior to dual PP devices. Based on a study by Gmeiner et al. [4], success (free of primary end point) rate is 0.73 and 0.46 with one PP plus one AngioSeal (AS) and dual PP devices, respectively.

To achieve 85% statistical power and keep one-sided type I error as 2.5%, and an equivalence margin of 5%, a sample size of n= 40 per group is required to detect if one PP plus one AS is non-inferior to dual PP devices. After adjusting for 10% dropout rate, a sample size of n=45 per group is required. The total sample size should be 90 if patients are randomized 1:1 to both groups.

13.4 Loss to Follow-up

Subjects lost to follow-up will be excluded from the analyses. Demographics and baseline characteristics will be compared between included and lost-to-follow-up subjects.

13.5 Interim Analysis

Once half of the patients have been enrolled and completed the study, an interim analysis will be conducted with the goal of monitoring safety and presence of adverse events.

14. PROCEDURES AND INSTRUCTIONS

14.1 Protocol Deviations

Deviations from this protocol will be reported to the IRB in the following manner:

- Unplanned deviations that do not increase the potential risk of the subject will be reported to the IRB at the Continuing Review
- Unplanned deviations that do have the potential of increasinig the risk of the subject will be reported to the IRB within 10 days of the deviation or becoming aware of the ocurrence.
- Emergency planned deviations (under the control of the research team), the study team will email the IRB within 24 hours of implementation and then the study team will send a report to the IRB within 10 days of implementation.

- Non-emergency planned deviations (under the control of the research team), the study team will report it to the IRB before implementation.

Study staff will keep a study specific protocol deviation log for tracking of all protocol deviations throughout the trial.

14.2 Protocol Amendments

Any substantive changes will be made as formal amendments to the protocol and will be submitted for appropriate review by the institutional review board (IRB).

These requirements for approval should in no way prevent any immediate action from being taken by the Investigator to ensure the safety of all subjects included in the study.

14.3 Recording of Data, Documentation, and Retention of Documents

Data will be stored and evaluated in such a way as to guarantee subject confidentiality in accordance with the legal stipulations applying to confidentiality of data. All study records must be available for inspection by the Sponsor (BSWRI), its authorized representatives, the FDA and other regulatory authorities.

Data on subjects collected for research purposes will be done securely and electronically on the BSWH REDCap system. A patient ID will be assigned and only approved research staff will have access to the study database.

The Investigator must maintain source documents for each subject in the study including a copy of the signed ICF.

14.4 Publication of Results

An integrated clinical and statistical report will be prepared at the completion of the treatment period. It is intended that the results of the study will be included on http://clinicaltrials.gov (if it is an applicable study) and published and/or presented at scientific meetings.

14.5 Disclosure and Confidentiality

The Investigator must assure that subjects' anonymity will be maintained and that their identities are protected from unauthorized parties. The Investigator will keep a subject enrollment log relating codes to the names of subjects. The Investigator should maintain documents not for submission to the Sponsor (Baylor Scott & White Research Institute), e.g., subjects' signed consent forms, in strict confidence.

14.6 Monitoring Plan

A member of the QA team will review the study at the following timepoints:
1. Within 30 business days of the 1st patient enrollment
2. After 50% enrollment
3. After 100% enrollment or nearing study closure

15. ETHICS AND GOOD CLINICAL PRACTICE

15.1 Institutional Review Board/Independent Ethics Committee

Before implementing this study, the protocol, the proposed informed consent form and other information to subjects will be reviewed by the BSWRI IRB. The Investigators will not begin any study subject activities until approval from the IRB has been documented and provided as a letter to the Investigator. Before implementation, the Investigators will submit to and receive documented approval from the IRB of any modifications made to the protocol or any accompanying material to be provided to the subject after initial IRB approval, with the exception of those necessary to reduce immediate risk to study subjects.

15.2 Informed Consent

Each subject will be informed that participation in the study is voluntary, that he/she may withdraw from the study at any time, and that withdrawal of consent will not affect his/her subsequent medical treatment or relationship with the treating physician.

This informed consent should be given by means of a standard written statement, written in nontechnical language. The study team may perform consent procedures over the phone after a subject is mailed or emailed the consent form. The subject should read and consider the statement before signing and dating it (wet ink or DocuSign), and should be given a copy of the signed document. No subject can enter the study before his/her informed consent has been obtained.

16. REFERENCES

1. Bazarbashi N, Ahuja K, Gad MM, Sammour YM, Kaur M, Karrthik A, Saad AM, Khubber S, Dhaliwal K, Mick SL, Navia JL, Puri R, Reed GW, Krishnaswamy A, Kapadia SR. The utilization of single versus double Perclose devices for transfemoral aortic valve replacement access site closure: Insights from Cleveland Clinic Aortic Valve Center. Catheter Cardiovasc Interv. 2020 Aug;96(2):442-447. doi: 10.1002/ccd.28585. Epub 2019 Nov 12. PMID: 31713996.
2. Ko TY, Kao HL, Liu YJ, Yeh CF, Huang CC, Chen YH, Hung CS, Chan CY, Lin LC, Chen YS, Lin MS. Intentional combination of ProGlide and Angio-Seal for femoral access haemostasis in transcatheter aortic valve replacement. Int J Cardiol. 2019 Oct 15;293:76-79. doi: 10.1016/j.ijcard.2019.05.055. Epub 2019 May 23. PMID: 31155328.
3. Kiramijyan S, Magalhaes MA, Ben-Dor I, Koifman E, Escarcega RO, Baker NC, Torguson R, Okubagzi P, Bernardo NL, Satler LF, Pichard AD, Waksman R. The adjunctive use of Angio-Seal in femoral vascular closure following percutaneous transcatheter aortic valve replacement. EuroIntervention. 2016 May 17;12(1):88-93. doi: 10.4244/EIJV12I1A16. PMID: 27173868.
4. Tobias Rheude, Hendrik Ruge, Niklas Altaner, Costanza Pellegrini, Hector Alvarez Covarrubias, N Patrick Mayr, Salvatore Cassese, Sebastian Kufner, Yousuke Taniguchi, Christian Thilo, Markus Klos, Magdalena Erlebach, Simon Schneider, Martin Jurisic, Karl-Ludwig Laugwitz, Rüdiger Lange, Heribert Schunkert, Adnan Kastrati, Markus Krane, Erion Xhepa, Michael Joner, Comparison of strategies for vascular ACCESS closure after transcatheter aortic valve implantation: the ACCESS-TAVI randomized trial, European Heart Journal, 2024;, ehae784, https://doi.org/10.1093/eurheartj/ehae784
5. Gmeiner JMD, Linnemann M, Steffen J, Scherer C, Orban M, Theiss H, Mehilli J, Sadoni S, Peterß S, Joskowiak D, Hagl C, Tsilimparis N, Curta A, Maurus S, Doldi PM, Löw K, Haum M, Roden D, Hausleiter J, Massberg S, Rizas K, Deseive S, Braun D. Dual ProGlide versus ProGlide and FemoSeal for vascular access haemostasis after transcatheter aortic valve implantation. EuroIntervention. 2022 Nov 18;18(10):812-819. doi: 10.4244/EIJ-D-22-00311. PMID: 35903846; PMCID: PMC9724847.
6. Winter MP, Bartko P, Hofer F, Zbiral M, Burger A, Ghanim B, Kastner J, Lang IM, Mascherbauer J, Hengstenberg C, Goliasch G. Evolution of outcome and complications in TAVR: a meta-analysis of observational and randomized studies. Sci Rep. 2020 Sep 23;10(1):15568. doi: 10.1038/s41598-020-72453-1. PMID: 32968104; PMCID: PMC7511292
7. Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG, Tuzcu EM, Webb JG, Fontana GP, Makkar RR, Williams M, Dewey T, Kapadia S, Babaliaros V, Thourani VH, Corso P, Pichard AD, Bavaria JE, Herrmann HC, Akin JJ, Anderson WN, Wang D, Pocock SJ; PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011 Jun 9;364(23):2187-98. doi: 10.1056/NEJMoa1103510. Epub 2011 Jun 5. PMID: 21639811.
8. Mach M, Okutucu S, Kerbel T, Arjomand A, Fatihoglu SG, Werner P, Simon P, Andreas M. Vascular Complications in TAVR: Incidence, Clinical Impact, and Management. J Clin Med. 2021 Oct 28;10(21):5046. doi: 10.3390/jcm10215046. PMID: 34768565; PMCID: PMC8584339.