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ORIGINAL ARTICLE

Ultrasound- Versus Fluoroscopy-Guided Strategy for Transfemoral Transcatheter Aortic Valve Replacement Access

A Systematic Review and Meta-Analysis

Rafail A. Kotronias, MBChB, MSc*; Jonathan J.H. Bray, MBChB, BSc*; Skanda Rajasundaram, BA; Flavien Vincent, MD, PhD; Cedric Delhaye, MD; Roberto Scarsini, MD; Federico Marin, MD; Dimitrios Terentes-Printzios, MD, PhD; Julian P.J. Halcox, MD, MB, BChir, BA; Mamas A. Mamas, BMBCh, DPhil; Rajesh Kharbanda, MD, PhD; Eric Van Belle, MD, PhD; Adrian P. Banning, MBBS, MD

BACKGROUND: Access site vascular and bleeding complications remain problematic for patients undergoing transcatheter aortic valve replacement (TAVR). Ultrasound-guided transfemoral access approach has been suggested as a technique to reduce access site complications, but there is wide variation in adoption in TAVR. We performed a systematic review and meta-analysis to compare access site vascular and bleeding complications according to the Valve Academic Research Consortium-2 classification following the use of either ultrasound- or conventional fluoroscopy-guided transfemoral TAVR access.

METHODS: Medline, Embase, Web of Science, and The Cochrane Library were searched to November 2020 for studies comparing ultrasound- and fluoroscopy-guided access for transfemoral TAVR. A priori defined primary outcomes were extracted: (1) major, (2) minor, and (3) major and minor (total) access site vascular complications and (4) life-threatening/major, (5) minor, and (6) life-threatening, major, and minor (total) access site bleeding complications.

RESULTS: Eight observational studies (n=3875) were included, with a mean participant age of 82.8 years, STS score 5.81, and peripheral vascular disease in 23.5%. An ultrasound-guided approach was significantly associated with a reduced risk of total (Mantel-Haenszel odds ratio [MH-OR], 0.50 [95% CI, 0.35–0.73]), major (MH-OR, 0.51 [95% CI, 0.35–0.74]), and minor (MH-OR, 0.59 [95% CI, 0.38–0.91]) access site vascular complications. Ultrasound guidance was also significantly associated with total access site bleeding complications (MH-OR, 0.59 [95% CI, 0.39–0.90]). The association remained significant in sensitivity analyses of maximally adjusted minor and total vascular access site complications (MH-OR, 0.51 [95% CI, 0.29–0.90]; MH-OR, 0.44 [95% CI, 0.20–0.99], respectively).

CONCLUSIONS: In the absence of randomized studies, our data suggests a potential benefit for ultrasound guidance to obtain percutaneous femoral access in TAVR.

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Key Words: fluoroscopy ■ morbidity ■ peripheral vascular diseases ■ punctures ■ transcatheter aortic valve replacement ■ ultrasound

Correspondence to: Adrian P. Banning, MBBS, MD, Oxford Heart Centre, John Radcliffe Hospital, Headley Way, OX3 7BA, Oxford, United Kingdom. Email adrian.banning@ouh.nhs.uk

*R.A. Kotronias and J.J.H. Bray contributed equally.

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WHAT IS KNOWN

- Ultrasound-guided transfemoral access has been suggested to reduce access site complications in transcatheter aortic valve replacement.

WHAT THE STUDY ADDS

- An ultrasound-guided approach for transcatheter aortic valve replacement access is associated with a 50% reduced risk of major and minor access site vascular complications and a ≈40% reduced risk of life-threatening, major, and minor access site bleeding complications.
- In the absence of randomized data, we recommend that ultrasound guidance is considered to obtain percutaneous transfemoral access in transcatheter aortic valve replacement.

Nonstandard Abbreviations and Acronyms

FCA	fluoroscopic contralateral access
TAVR	transcatheter aortic valve replacement
MH-OR	Mantel-Haenszel odds ratio

Despite procedural advances in transcatheter aortic valve replacement (TAVR), vascular and bleeding complications remain problematic.[1] According to a recent meta-analysis of studies using contemporary tissue heart valve systems, access site vascular and bleeding complications are encountered in up to 10% and 14% of TAVR cases, respectively.[2] Moreover, the occurrence of access site complications are known to be associated with higher rates of morbidity and mortality[3] and increased costs associated with prolonged length of stay.[4]

Transfemoral TAVR access is the preferred access site for >90% of TAVR procedures and has historically been obtained using anatomic landmarks and fluoroscopic guidance via opacification of the common femoral artery from the contralateral (secondary) access—fluoroscopic contralateral access (FCA) technique.[5] Ultrasound-guided transfemoral access has been proposed as an alternative strategy to reduce access site complications,[6] as it offers real-time, cross-sectional visualization of the puncture site anatomy reducing accidental vascular injury and enhancing the efficacy of vascular closure devices.[7] Ultrasound has been recommended by some Interventional Society Guidelines,[8] but there is currently, no conclusive data confirming whether an ultrasound-guided transfemoral access strategy confers superior outcomes to an FCA strategy during TAVR. Therefore, we set out to perform a systematic review and meta-analysis to assess the evidence for access site vascular and bleeding complication rates comparing the use of either modality to guide transfemoral access in TAVR.

METHODS

This review is written in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement[9] and is registered with PROSPERO. Ethical approval was not sought because of the systematic review and meta-analysis nature of this study.

Search Strategy

The search strategy used for this study is presented in the methods in the Data Supplement.

Study Selection

We selected studies that compared ultrasound- and fluoroscopy-guided transfemoral access, with 2 groups of participants pertaining to each intervention. We excluded TAVR by any other route, any studies referring to nonaccess site related complications, pediatric operations, and any study which could not be quantitatively assessed through meta-analysis. No limits were set on language.

Outcomes of Interest and Comparisons

We defined the following primary end points a priori: (1) major, (2) minor and (3) total (major and minor) access site vascular complications, (4) life-threatening and major, (5) minor, and (6) total (life-threatening, major and minor) access site bleeding complications. We defined a priori the requirement for red blood cells transfusion as a secondary end point. Where possible, adjusted end point data were collected. Where relevant end point data was missing, where possible, it was sought from corresponding authors via email or by search of data repositories. Complications were included if recorded in accordance with the Valve Academic Research Consortium-2 standardizing end point reporting system.[10]

Data Extraction and Synthesis

Data were independently transferred from full manuscripts into preformatted tables by 2 reviewers (J.J.H. Bray and S. Rajasundaram). The extraction process is described in more detail in methods in the Data Supplement. The authors declare that all supporting data are available within the article and in the Data Supplement.

Quality and Risk of Bias Assessment

The Cochrane Risk of Bias in Nonrandomised Studies of Interventions tool was used to assess risk of bias.[11] Degree of confidence in the influence of ultrasound- or fluoroscopy-guidance on selected outcomes was assessed using the Grading of Recommendations Assessment, Development and Evaluation tool.[12]

Statistical Analysis

Data are presented as mean or median, unless stated otherwise. Study end points were analyzed using Mantel-Haenszel random effects meta-analyses (Review Manager [RevMan] 5.3, Copenhagen: The Nordic Cochrane centre 2014). I^2 statistics were calculated to assess for evidence of significant heterogeneity. An alpha value of <0.05 was considered statistically significant. The robustness of the data analyzed, analysis methods, and heterogeneity was explored with sensitivity analyses. Heterogeneity was explored in meta-analyses of outcomes with evidence for substantial heterogeneity ($I^2 \geq 50\%$) using the sequential study removal algorithm and a desired I^2 threshold of <50%.[13]

RESULTS

Our search identified 1844 articles. Eight observational studies were considered eligible (Figure 1), collectively consisting of 3875 participants (median, 458; range, 154–1171).[6,7,14–21] Seven of the included studies (n=3488) were published between 2019 and 2020,[7,15–19,21] and at least 7 (n=3043) included contemporary generation valve types.[6,7,16,17,19,21] Data was available from full texts in 6 studies,[6,7,14,17,19,21] from a research letter in one study[18] and from an abstract in one study.[16] As the full text for the study by Bouteau et al[14,15] was only available as a thesis in French, it was translated into English before data extraction. Since the study by Potluri et al[19] did not report sufficient data to ascertain access site related bleeding complications, bleeding outcomes were taken from Basra et al[20]; a study from the same center and authors with an overlapping study time periods that provided sufficient data to adjudicate bleeding events as access site related.

The studies were from international centers and populations (2 United Kingdom, 2 France, 1 Australia, 1 Canada, 1 Finland, and 1 United States). Characteristics of included studies were overall generalizable and comparable (Table). Participants from included studies had a mean age of 82.8 years and 49.8% were female. In addition to the characteristics shown in Table and Table I in the Data Supplement, participants had a Society of Thoracic Surgeons score of 5.81, 30.4% had diabetes, 23.5% had peripheral vascular disease, and 48.6% had coronary artery disease. Four studies indicated that TAVR was performed by experienced operators[6,14,19,21] while all other studies did not specify operator experience.

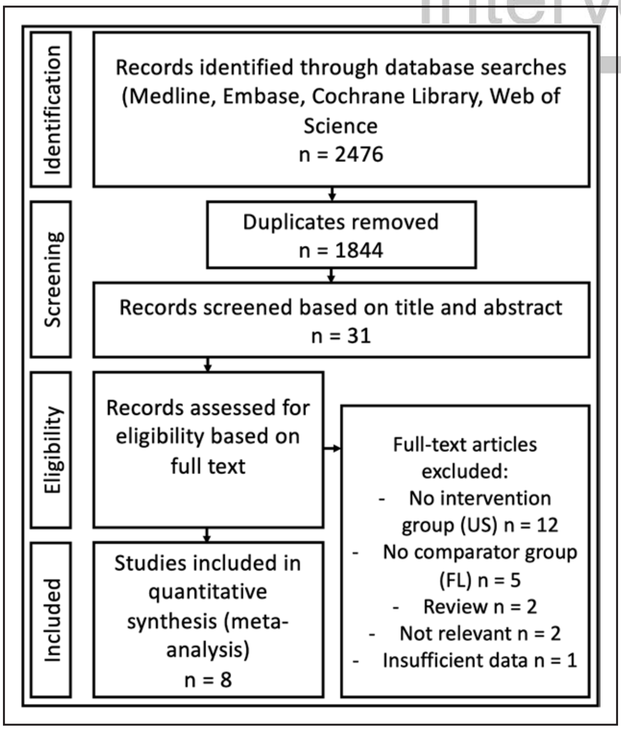

Figure 1. Flow diagram based on PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses).[9]
FL indicates fluoroscopy; and US, ultrasound.

Risk of Bias and Quality Assessment

Included studies used record linkage or active follow-up for outcome ascertainment.[6,7,14,17,21] In articles that referred to missing data, it was reported as being <5% and controlled for adequately.[6,7,14] Four studies adjusted end points of interest for multiple confounders, either through multivariate analysis[17,21] or through propensity matching.[7,18] Using the Risk of Bias in Nonrandomised Studies of Interventions tool, we identified 4 studies at moderate risk of bias[7,17,18,21] and 4 at serious risk of bias (Table II in the Data Supplement).[6,14,16,19] The driver of serious and moderate risk of bias in all cases was adjustment for confounders. One study only adjusted for Society of Thoracic Surgeons score.[14] Moderate risk of bias was also driven by inadequate blinding relating to data handling in most cases.[6,7,17,21] The appraisal of our evidence according to the GRADE tool was deemed as of very low certainty owing to the observational nature of the included studies (Table III in the Data Supplement).

Access Site Vascular Complications

Crude event rates are shown in Table IV in the Data Supplement. Crude major and minor (total) access site vascular complications were ascertained in 7 studies and occurred in 12.2% (451/3710) of patients.[6,7,14,17–19,21] Crude major access site vascular complications were reported in 8 studies and occurred in 5.5% (211/3864) of patients.[6,7,14,16–19,21] Minor access site vascular complications were ascertained in 7 studies and occurred in 6.6% (244/3710) of patients.[6,7,14,17–19,21]

In aggregate level meta-analyses of up to 8 studies (n=3864),[6,7,14,16–19,21] use of ultrasound guidance for transfemoral access in TAVR procedures was associated with significant reductions in the risk of total, major, and minor access site vascular complications (Figure 2). The strongest associations were observed in reduction of total and major access site vascular complications (Mantel-Haenszel odds ratio [MH-OR], 0.50 [95% CI, 0.35–0.73], I^2=65%, n=7 and MH-OR, 0.51 [95% CI, 0.35–0.74], I^2=30%, n=8, respectively). Similarly, minor access site vascular complications reductions were associated with an ultrasound-guided approach (MH-OR, 0.59 [95% CI, 0.38–0.91], I^2=56%, n=7).

Table. Study Design Features and Key Characteristics

Study (first author, year)	Participants included (n)	Sheath sizes (Fr)	Valve type	Ultrasound technique	Temporal relation of compared cohorts*
Kotronias, 2020[17]	529	14–20	SAPIEN 3, Lotus, Corevalve, AcurateNeo	Long axis	Sequential
Potluri, 2020[19]	612	14–20	SAPIEN 3, Evolut-R	Short axis	Sequential with overlap
Vincent, 2020[7]	190	14–19	SAPIEN XT, SAPIEN 3, Corevalve, Evolut-R	Short+long axis	Sequential
Witberg, 2020[21]	1171	14–20	SAPIEN XT, SAPIEN 3, Evolut-R, Lotus, ACCURATE neo, Portico	Short+long axis	Parallel
Bouteau, 2019[14]	573	…	Corevalve (59.6%)	…	Sequential
Moriyama, 2019[18]	246	…	…	Long axis†	…
Khan, 2019[16]	154	14–16	SAPIEN 3	…	…
Elbaz-Greener, 2017[6]	387	14–20	SAPIEN XT, SAPIEN 3, Lotus, Evolut-R, Portico, Corevalve,	…	Sequential

Fr indicates French.
*Sequential indicates fluoroscopy cohort preceded ultrasound cohort. Parallel design is reported to mitigate against temporal bias.
†Inference of technique from figure representation.

Access Site Bleeding Complications

Crude event rates are shown in Table IV in the Data Supplement. Crude life-threatening, major and minor (total) access site bleeding complications were ascertained in 5 studies and occurred in 11.0% (274/2490) of patients.[6,7,17,20,21] Crude life-threatening and major access site bleeding complications were reported in 6 studies and occurred in 5.9% (162/2760) of patients.[6,7,17,18,20,21] Minor access site bleeding complications were ascertained in 5 studies and occurred in 5.1% (126/2490) of patients, respectively.[6,7,17,20,21]

In aggregate level meta-analyses of up to 6 studies with 2760 participants,[6,7,17,18,20,21] the adoption of ultrasound guidance for TAVR transfemoral access was associated with a significant reduction in the risk of total access site bleeding complications (MH-OR, 0.59 [95% CI, 0.39–0.90], I^2=52%, n=5). Ultrasound guidance was also associated with reductions in the risk of life-threatening and major, and minor access site bleeding complications but these did not reach statistical significance (MH-OR, 0.52 [95% CI, 0.26–1.04], I^2=69%, n=6 and MH-OR, 0.67 [95% CI, 0.34–1.31], I^2=59%, n=5, respectively; Figure 3).

Transfusion of Red Blood Cells

Only 3 studies reported data on requirement for transfusion of at least 1 unit of red blood cells (1748 participants), which reached a crude rate of 8.3% (146/1748).[6,7,21] There was no significant association of ultrasound- or fluoroscopy-guided transfemoral approach with blood transfusion requirement.

Sensitivity Analysis

We conducted sensitivity analysis of the data analyzed, bias severity, analysis methodology implemented, and heterogeneity observed, as summarized in Table V in the Data Supplement. Maximally adjusted minor and total access site vascular complications remained significant with a comparable effect estimate (MH-OR, 0.51 [95% CI, 0.29–0.90], I^2=21%, n=4 and MH-OR, 0.44 [95% CI, 0.20–0.99], I^2=75%, n=4, respectively; Table V in the Data Supplement and Figure 4).[7,17,18,21] Whereas, maximally adjusted major access site vascular complications became marginally nonsignificant maintaining a comparable effect direction and size (MH-OR, 0.49 [95% CI, 0.24–1.02], I^2=75%, n=4; 23, 26–28). The direction of the effect estimates for maximally adjusted access site bleeding complications remained the same but was only based on 2 studies per end point (Tables V and VI and Figure I in the Data Supplement).[7,18,21]

The reduction of heterogeneity to below 50% led to an increase in the magnitude of the ultrasound-guided strategy effect estimate for life-threatening/major and total access site bleeding complications (Table V in the Data Supplement). Consequently, in this homogeneous study subgroup ultrasound-guided strategy was significantly associated with reductions in life-threatening and major bleeding complications. Minor bleeding complications were associated with either access guidance strategy. The magnitude of the effect estimate for total vascular complication was greater, but the reduction in minor vascular complications became not significant (Table V in the Data Supplement). Finally, the direction of the effect estimate did not change upon exclusion of studies at severe risk of bias (Table V in the Data Supplement).

DISCUSSION

The main finding of this meta-analysis of 8 observational studies is that ultrasound-guided access for transfemoral TAVR is associated with a 50% and ≈40% reduction in the risk of access site vascular and bleeding complications, respectively. Although the study synthesizes data from low-moderate quality studies, sensitivity analysis including maximally adjusted results shows that

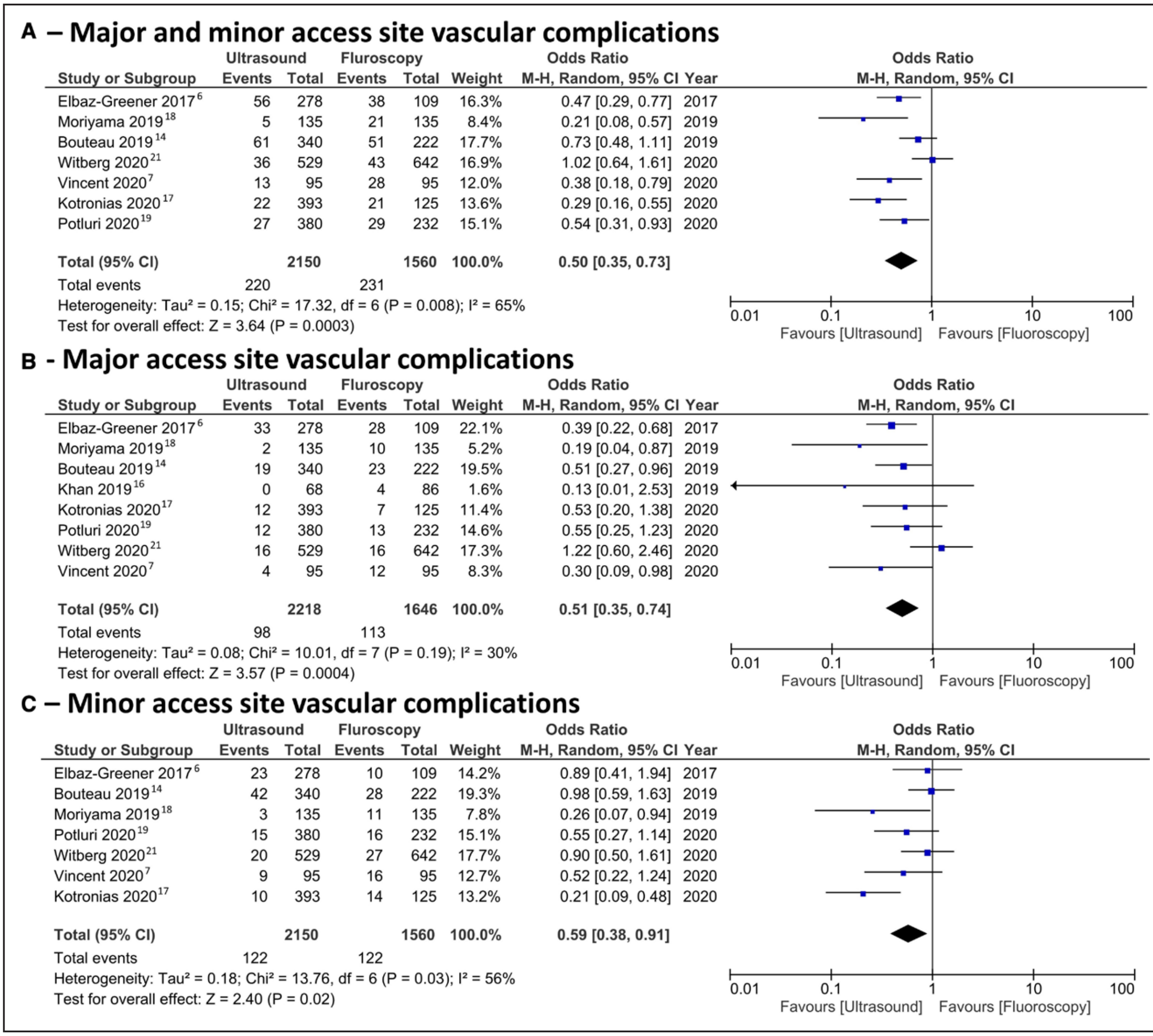

Figure 2. Meta-analyses evaluating risk of access site vascular complications of an ultrasound-guided vs fluoroscopy-guided transcatheter aortic valve replacement access strategy.

Major and minor access site vascular complications (**A**), major access site vascular complications (**B**), and minor access site vascular complications (**C**). M-H indicates Mantel-Haenszel.

ultrasound guidance is associated with a significant 56% reduction in access site vascular complications. In the absence of randomized studies, the current study represents an important synthesis of available evidence and should inform clinical practice.

Femoral Artery Access Techniques and Modifications

Historically, transfemoral TAVR access has been obtained using anatomic landmarks under fluoroscopic guidance—the FCA technique.[5] Based on the substantial literature supporting the adoption of a transradial approach for percutaneous coronary intervention,[22] the FCA technique has been modified to establish secondary access via a radial route.[23] A meta-analysis of 6 observational studies showed that this modification was associated with lower risk of major vascular and bleeding complications.[24] This is relevant as up to a quarter of vascular and bleeding access complications are attributed to the secondary vascular access site.[25]

Role of Ultrasound Guidance in Percutaneous Large-Bore Arterial Access

Ultrasound guidance for percutaneous arterial access offers a real-time, high spatial resolution, and radiation-free technique to study the anatomy of the vascular tree. Ultrasound guidance for procedures requiring percutaneous large-bore arterial access (eg, TAVR, ventricular assist devices, endovascular aneurysm repair) is of considerable clinical relevance as it prevents inadvertent

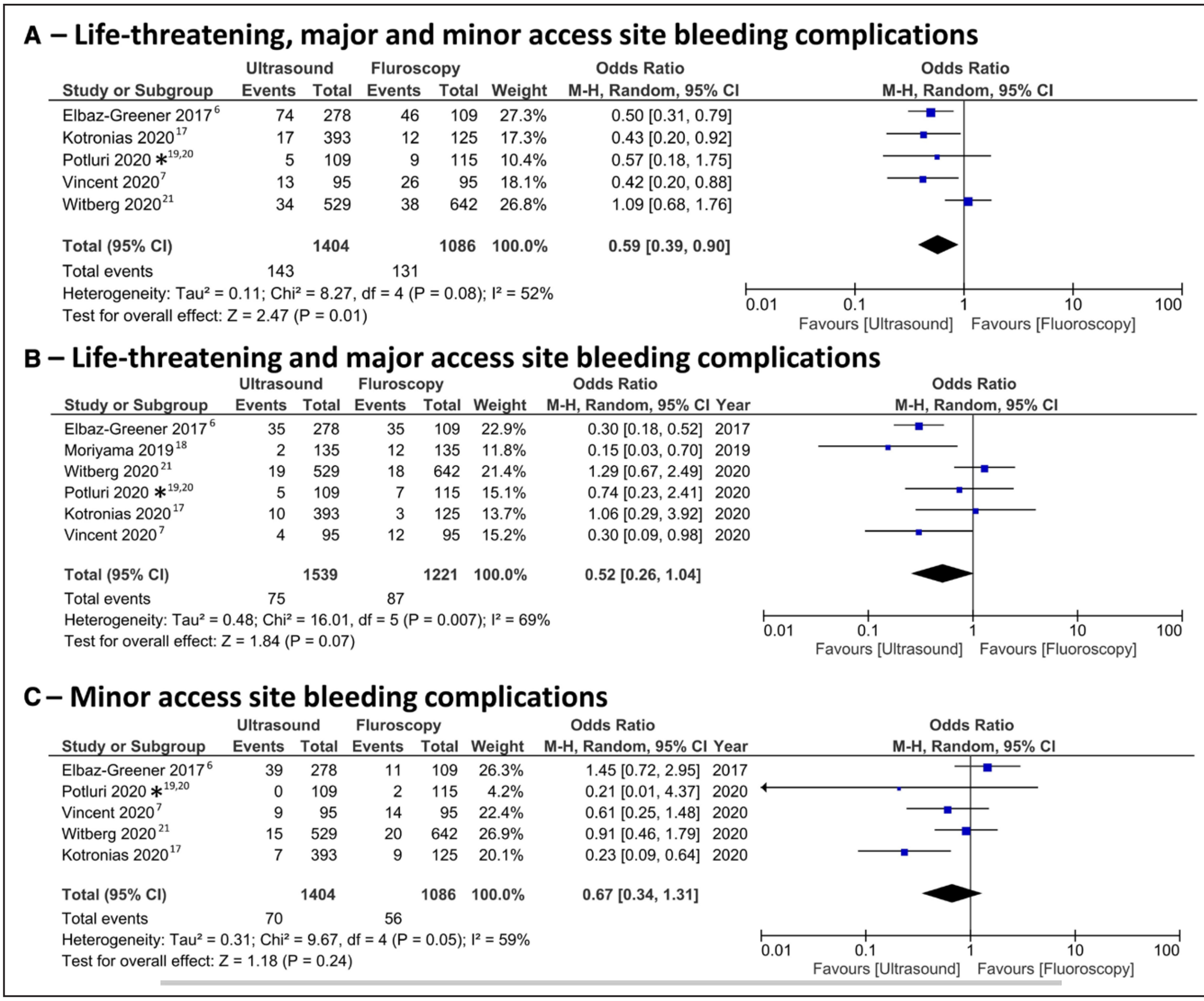

Figure 3. Meta-analyses evaluating risk of access site bleeding complications of an ultrasound-guided vs fluoroscopy-guided transcatheter aortic valve replacement access strategy.

Life-threatening, major and minor access site bleeding complications (**A**), life-threatening and major access site bleeding complications (**B**), and minor access site bleeding complications (**C**). *Since the study by Potluri et al[19] did not report sufficient data to ascertain access site-related bleeding complications, bleeding outcomes were taken from Basra et al[20]; a study from the same center and authors with a overlapping study time periods that provided sufficient data to adjudicate bleeding events as access site-related. M-H indicates Mantel-Haenszel.

arterial injury and enhances the efficacy of percutaneous vascular closure, modifying the risk of access site vascular and bleeding complications.[7]

Impact of Ultrasound Guidance on Access Site Complications

The impact of ultrasound-guided femoral artery access on access site complications has been investigated extensively for coronary angiography/percutaneous coronary intervention[26] but less so for large-bore arterial access procedures.[27] Despite the conflicting evidence regarding the role of ultrasound guidance for coronary angiography, a recent meta-analysis of randomized controlled trials showed that ultrasound guidance was associated with a reduction in bleeding events.[28] The results of our meta-analysis are consistent with this finding. The adoption of ultrasound by centers in our meta-analysis was associated with almost halving of vascular and bleeding complications.

This association remained significant for both major and minor access site vascular complications. However, the association of ultrasound guidance with bleeding complications reduction was no longer statistically significant when total access site bleeding complications were separated into life-threatening and major, and minor access site complications. This may partly be attributed to between study heterogeneity and the insufficient power of the meta-analysis due to the low number of bleeding events. The lower number of events when compared with vascular complications is expected since access site bleeding is usually due to an access site vascular injury[7] and is within rates described in contemporary literature.[3] In an era of

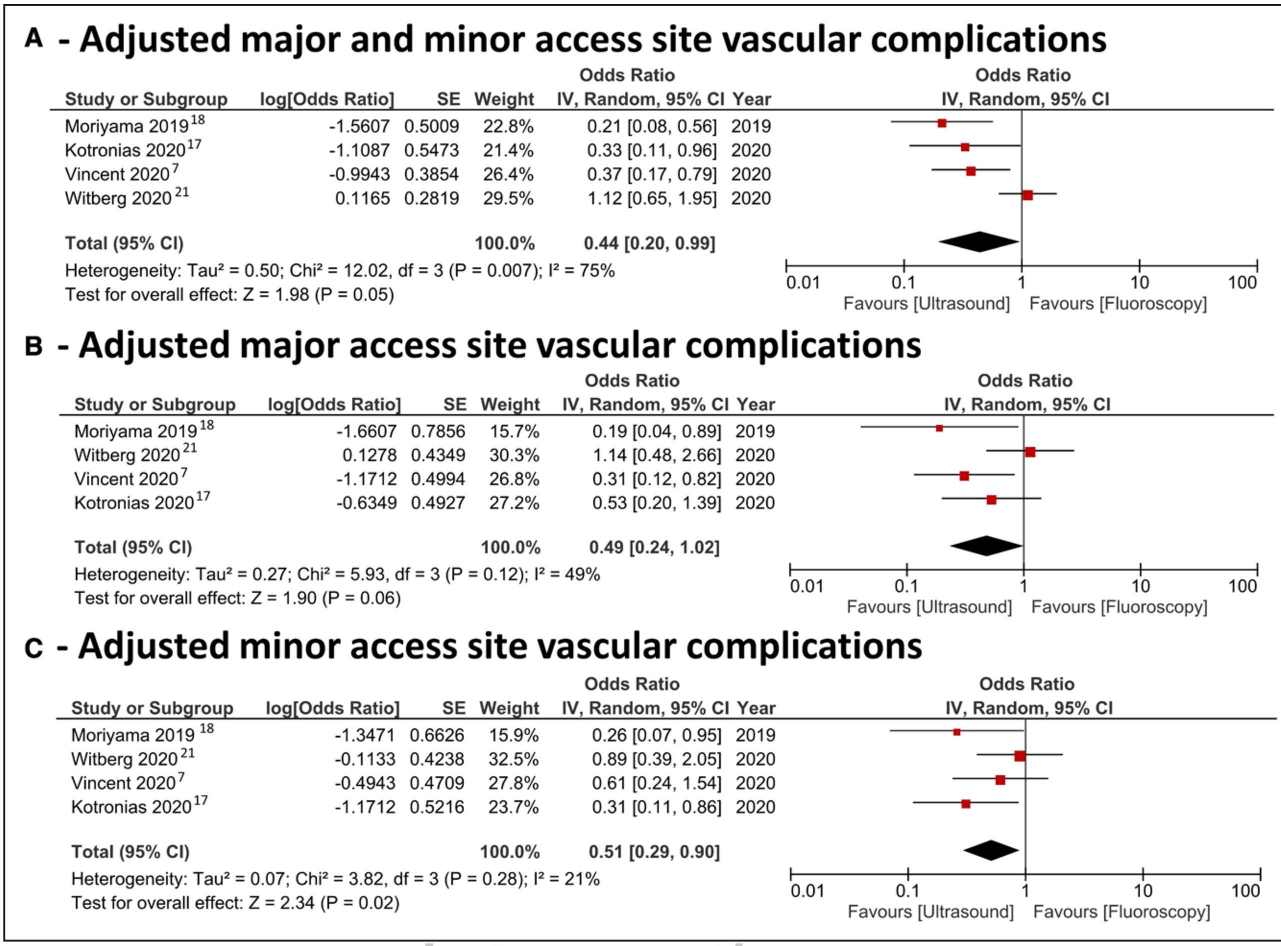

Figure 4. Meta-analyses evaluating maximally adjusted risk of access site vascular complications of an ultrasound-guided vs fluoroscopy-guided transcatheter aortic valve replacement access strategy.
Major and minor access site vascular complications (**A**), major access site vascular complications (**B**), and minor access site vascular complications (**C**). IV indicates inverse variance.

increasing operator experience in detecting and managing vascular complications,[29] access site bleeding complications would less frequently reach the clinical detectability or severity threshold that allows their ascertainment as Valve Academic Research Consortium-2 end points.

Implications for Clinical Practice

The results of our meta-analysis support the routine adoption of ultrasound to guide primary access in TAVR as a tool that can modify the risk of vascular and bleeding complications. This is particularly important in the TAVR setting, as patients are elderly and comorbid and at higher risk of sustaining access site related bleeding complications, than the younger patient groups that undergo femoral access for coronary angiography/percutaneous coronary intervention indications. Reducing access site complications should lead to reductions in the associated morbidity and mortality,[1,3] and streamline discharge pathways reducing postoperative length of stay.[30] As TAVR expands to lower risk and younger patients with severe aortic stenosis, further reducing access site complications with simple, resource neutral modifications can improve the risk-benefit and cost-effectiveness profile of TAVR.

A study by Witberg et al[21] suggested that in the hands of experienced femoral operators in tertiary centers with low vascular and bleeding complication rates (<7%, respectively) an FCA strategy could match an ultrasound-guided strategy. While recognizing the validity of this comparison by expert operators in expert centers, it is possible to assert that using ultrasound is likely to be a more readily trainable and exportable technique. This is an important consideration as the volume of TAVR increases and as new implantation centers are considered. Finally, our results are applicable to other procedures requiring percutaneous large-bore access (eg, endovascular aneurysm repair, ventricular assist device-supported percutaneous coronary intervention).

Limitations

First, our study is an aggregate level meta-analysis based on low-moderate quality observational studies, subject to residual confounding from unadjusted factors such as peripheral arterial disease, radial secondary access, vascular closure device type and number, and sheath to femoral artery ratio. To explore the influence of confounding, we performed sensitivity analyses including studies of maximally adjusted vascular complications (propensity-matched or multivariate adjusted outcomes) which showed that the direction of the effect estimate did not change. Second, our study includes one study that has been presented as an abstract though its inclusion highlights our attempt to minimize the effects of publication bias. Third, the studies included in this meta-analysis lacked the granularity to ascertain the primary end points as primary or secondary access related. They also do not provide sufficient information to explore vascular closure device failure.

In addition, the time frame of study conduct was heterogeneous including patients recruited from 2012 onwards. This introduces temporal bias related to learning curves and advances in TAVR technology and patient care over time. Unfortunately, we were not able to test for temporal trends as the available data lack this level of granularity. Nonetheless, 2 studies test the temporal effect and found no association with the risk of adverse outcomes[17,21] while other studies adjust for factors (eg, sheath size) associated with procedural advances.[7,19] Finally, there is evidence of substantial heterogeneity in some of our meta-analyses. Our heterogeneity sensitivity analysis shows that the direction of the primary end points effect estimates did not change when heterogeneity (I^2) was reduced to <50% or studies at serious risk of bias were excluded. Nonetheless, many factors can explain the between study heterogeneity that is observed. From a patient perspective, the reported prevalence of peripheral arterial disease varies from 6% to 47.2%.[14,17] We also note a considerable between study heterogeneity of the delivery profile of the implanted systems. One study included first generation systems,[6] while others included Acurate Neo and Lotus tissue heart valves that require larger delivery sheaths.[17,21] Equally, the complication rates of the study by Witberg et al[21] are comparatively low contributing significantly to the observed heterogeneity in total and major access site vascular and bleeding complications. Despite these limitations, this is the first synthesis of available literature in the field, presenting clinically significant findings that remain to be confirmed in a randomized study.

Conclusions

Our aggregate level meta-analysis of low-moderate quality observational studies presents a clinically important synthesis of evidence for contemporary TAVR practice. The reported significant association of an ultrasound-guided access approach with reductions in total vascular and bleeding access site complications by 50% and ≈40%, respectively, has important patient-oriented ramifications for all vascular procedures requiring large-bore percutaneous access. We propose a randomized trial comparing ultrasound to fluoroscopy-guided percutaneous transfemoral access in TAVR to provide high level evidence. In the interim considering the resource neutral nature of ultrasound guidance and the reducing familiarity of operators with fluoroscopy-guided femoral access, ultrasound guidance should be considered to obtain percutaneous access in TAVR.

ARTICLE INFORMATION

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Affiliations

Oxford Heart Centre, Oxford University Hospitals, NHS Trust, United Kingdom (R.A.K., J.J.H.B., S.R., R.S., F.M., D.T.-P., R.K., A.P.B.). Department of Cardiovascular Medicine, University of Oxford, United Kingdom (R.A.K.). Institute of Life Sciences 2, Swansea Bay University Health Board and Swansea University Medical School, United Kingdom (J.J.H.B., J.P.J.H.). University Hospital of Wales, Cardiff and Vale University Health Board, United Kingdom (J.J.H.B.). Centre Hospitalier Universitaire de Lille-Cardiologie, France (F.V., C.D., E.V.B.). Department of Medicine, Division of Cardiology, University of Verona, Italy (R.S.). Keele Cardiovascular Research Group, Centre for Prognosis Research, Keele University, UK and Heart Centre, Thomas Jefferson University, Philadelphia (M.A.M.).

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Supplemental Materials

Expanded Methods
Online Tables I–VI
Online Figure I

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