A Comparison of Figure-of-8-Suture vs Manual Compression for Venous Access Closure after Cardiac Procedures: An Updated Meta-Analysis.

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Abstract

Background Manual compression (MC) is the current standard to achieve post-procedural hemostasis in patients who need venous vascular access closure after cardiovascular procedures. Figure-of-8 (F8) suture for venous access closure has been reported to be a safe and efficacious alternative to MC. Methods A systematic search was done using PubMed, Google Scholar, EMBASE, SCOPUS and ClinicalTrials.gov without language restriction up until April 15, 2020 for studies comparing F8 suture vs MC. Risk ratio (RR) and mean difference (MD) with 95% confidence interval (CI) were calculated using a random effects model. Results Time to achieve hemostasis was significantly reduced in the F8 arm [MD -21.04 mins (95% CI: -35.66 to -6.42; p=.005)]. Access site bleeding was significantly lower in the F8 group [RR 0.35 (95% CI: 0.18 to 0.66; p=0.001)] along with a lower incidence of hematoma formation [RR 0.42 (95% CI 0.26 to 0.67; p=0.0003)]. There was no significant difference in rates of fistula or pseudoaneurysm formation between the two groups. Overall access site complications were lower in the F8 arm [RR 0.38 (95% CI: 0.26 to 0.55; p<0.00001)] and the effect was more pronounced for sheaths [?]10 Fr [RR 0.33 (95% CI: 0.18 to 0.60; p=0.0003)]. There was lower post-procedural protamine use in the F8 group [RR 0.07 (95% CI:0.01 to 0.36; p=0.001)]. Conclusion For large-bore venous access closure, the F8 suture results in a shortened time to achieve hemostasis along with a lower overall risk of access site complications and post-procedural protamine use.

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MM, AA and YS conceptualized the work, gathered and interpreted the data, and drafted the initial manuscript. JF created the tables and figures. PR performed a critical revision of the manuscript.

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ABSTRACT

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Methods

A systematic search was done using PubMed, Google Scholar, EMBASE, SCOPUS and ClinicalTrials.gov without language restriction up until April 15, 2020 for studies comparing

F8 suture vs MC. Risk ratio (RR) and mean difference (MD) with 95% confidence interval (CI) were calculated using a random effects model.

Results

Time to achieve hemostasis was significantly reduced in the F8 arm [MD -21.04 mins (95% CI: -35.66 to -6.42; p=.005)]. Access site bleeding was significantly lower in the F8 group [RR 0.35 (95% CI: 0.18 to 0.66; p=0.001)] along with a lower incidence of hematoma formation [RR 0.42 (95% CI 0.26 to 0.67; p=0.0003)]. There was no significant difference in rates of fistula or pseudoaneurysm formation between the two groups. Overall access site complications were lower in the F8 arm [RR 0.38 (95% CI: 0.26 to 0.55; $p<0.00001$)] and the effect was more pronounced for sheaths [?]10 Fr [RR 0.33 (95% CI: 0.18 to 0.60; p=0.0003)]. There was lower post-procedural protamine use in the F8 group [RR 0.07 (95% CI:0.01 to 0.36; p=0.001)].

Conclusion

For large-bore venous access closure, the F8 suture results in a shortened time to achieve hemostasis along with a lower overall risk of access site complications and post-procedural protamine use.

Introduction

In patients undergoing cardiac procedures, the use of large sheath sizes for venous vascular access is not uncommon. Manual compression is the current standard to achieve post-procedural hemostasis. Although some studies have previously reported favorable outcomes in utilizing arterial vascular closure devices for venous access closure, data on venous vascular closure devices are limited.

Figure-of-8 (F8) suture is an alternative approach for large-bore venous access closure. Prior studies have evaluated the safety and efficacy of the F8 suture technique through venography or vascular ultrasound. (1-3) The first reported use of the F8 suture was done by Bagai and Zhao who used the technique to achieve adult femoral venous access hemostasis and reported success in large caliber sheaths (8 to 21 Fr). As a result, F8 has been used in achieving venous hemostasis with sheaths as large as 24 Fr. (1)

In the F8 suture, a large curved needle with a 0-silk suture is passed through the subcutaneous tissue around 5-10 mm under the access sheath with care taken not to insert the needle deep enough as to ligate the femoral vein or artery. A significant amount of subcutaneous tissue is included to contribute to compression and hemostasis. The needle is then brought cranially to the sheath insertion point and is inserted again in the same initial direction through the subcutaneous tissue, hence a figure of eight stitch is performed **[Figure 1].** After the sheaths are removed, the suture is tightened and knotted. The site is observed for a few minutes without utilization of manual compression. A sterile gauze is placed followed by monitoring for any signs of bleeding. Sutures are typically removed the following morning. (4-6)

Our study sought to determine the efficacy, impact and safety of F8 suture in comparison to manual compression for large-bore venous access closure. Nine studies composed of seven observational and two randomized controlled trials (RCTs) have been included in this updated meta-analysis.

Methods2.1 Search Strategy

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines was used in this meta-analysis. A systematic search was done using PubMed, Google Scholar, EMBASE, SCOPUS and ClinicalTrials.gov without language restriction up until April 15, 2020 by two authors (MM and AA). Studies comparing figure-of-8 suture vs manual compression were compared. The search included the following keywords: manual compression, manual pressure, figure of eight, figure of 8, fellow's stitch, z-stitch, venous closure, vascular closure.

2.2 Study Selection

The following criteria were used for study selection: [1] The study was performed on adults [?] 18 years of age. [2] The study compared figure-of-eight suture vs manual compression. [3] The study reported atleast one clinical outcome.

2.3 Data Extraction

Disagreements between the two authors (MM and AA) were resolved through internal discussion. The following details were collected from each study: Author, design, study population, male sex, age, mean CHA2DS2VASc score, laboratory parameters such as pre-procedural international normalized ratio (INR) and post-procedural activated clotting time (ACT), type of procedure, location of access sites, number of access sites and procedural success rate.

2.4 Clinical Outcomes

The study collected and evaluated the following clinical outcomes: [1] time to hemostasis [2] access site complications [3] fistula formation [4] pseudoaneurysm formation [5] access site bleeding [6] access site hematoma [7] post-procedural protamine use.

2.5 Statistical Analysis

Review Manager (RevMan), version 5.3 (The Cochrane Collaboration, Copenhagen, Denmark) was used for statistical analysis. The DerSimonian-Laird random-effects model was used to estimate the risk ratios (RR) and mean difference (MD) with the corresponding 95% confidence interval (CI). Two-sided p values <0.05 were considered statistically significant. Higgins and Thompson I^2 statistic was used to assess heterogeneity.

Results3.1 Search Results

A PRISMA flow chart has been included **[Figure 2].** A total of 121 citations were identified after an intensive search process, 23 articles were assessed for eligibility and 14 were excluded after screening. Nine studies were found to be eligible based on the inclusion criteria.(4-12)

3.2 Study Characteristics

In this meta-analysis, 9 eligible studies were included, composed of 7 observational and 2 RCTs with a total of 2,338 patients. The majority of the study population were males. 1,175 (50.26%) of patients received the F8 suture of which mean ± SD age ranged from 55 ± 12.4 to 63 ± 11 years and baseline INR ± SD ranged from 1.4 ± 0.5 to 2.6 +- 0.6. The majority of the procedures done were AF catheter ablation. Access sites reported were the left and right femoral veins. The success rate of the F8 suture ranged from 91.7% to 100% in the included studies

[Table 1].

3.3 Outcomes

3.3.1 Time to Hemostasis

Time to achieve hemostasis was significantly reduced in the F8 arm [MD -21.04 mins (95% CI: -35.66 to -6.42; p=.005)] **[Figure 3.1]** .

3.3.2 Overall Access Site Complications

Overall access site complications were lower in the F8 arm [RR 0.38 (95% CI:0.26 to 0.55; p<0.00001)] **[Figure 3.2]** .

3.3.3 Access Site Complications for Sheaths [?] 10 Fr

Access site complications for sheaths [?]10 Fr were lower in the F8 arm [RR 0.33 (95% CI: 0.18 to 0.60; p=0.0003)] **[Figure 3.3].**

3.3.4 Fistula Formation

There was no significant difference in the rate of fistula formation [RR 0.67 (95% CI: 0.18 to 2.41; p=0.54)] between the two groups**[Figure 3.4]** .

3.3.5 Pseudoaneurysm Formation

There was no significant difference in the occurrence of pseudoaneurysm [RR 0.47 (95% CI 0.16 to 1.42; p=0.18)] **[Figure 3.5]** .

3.3.6 Access site Hematoma

Access site hematoma formation was lower in the F8 arm [RR 0.42 (95% CI: 0.26 to 0.67; p=0.0003)] **[Figure 3.6]** .

3.3.7 Access Site Bleeding

Access site bleeding was significantly lower in the F8 group [RR 0.35 (95% CI: 0.18 to 0.66; p=0.001)] **[Figure 3.7]** .

3.3.8 Post-Procedural Protamine Use

Use of protamine after the procedure was significantly lower in the F8 arm [RR 0.07 (95% CI:0.01 to 0.36; p=0.001)] **[Figure 3.8]** .

Test of heterogeneity was low for rates of fistula, hematoma and pseudoaneurysm formation, and access site complications. Test of heterogeneity was moderate for access site bleeding and was high for time to achieve hemostasis and post-procedural protamine use.

Discussion

The main findings of our study are the following: [1] Time to achieve hemostasis was significantly shorter in the F8 group. [2] There is no difference between F8 and MC in pseudoaneurysm or fistula formation. [3] Access site hematoma and access site bleeding were lower in the F8 group . [4] Overall access site complications were lower in the F8 group with a more pronounced effect seen in sheaths [?] 10 Fr. [5] Post-procedural protamine use was higher in the manual compression group.

Vascular access site complications are known to occur in cardiac procedures and are associated with increased morbidity and prolonged hospital stay. (13, 14) The use of large venous sheaths, periprocedural anticoagulation and multiple sites of puncture contribute to these complications. A demographic shift towards elderly patients receiving cardiac procedures can contribute to an increase in complication rates. Techniques to achieve effective hemostatic control are thus of paramount importance to prevent these complications. Manual compression is the current standard for venous access closure and has been demonstrated to be effective in achieving post-procedural hemostasis; however, its use is associated with patient discomfort, need for additional staff and a longer patient stay in the procedural lab. (15) A period of absolute bed rest with limited limb movement is required to achieve hemostasis through MC. Various techniques such as pressure dressing and closure devices have been utilized for venous vascular hemostasis and have been reported to be efficacious. These techniques are associated with increased cost, risk of device failure and reported complications such as infections and thromboembolism.(16-22)

The F8 suture has been branded as the "*Fellow's Stitch* " due to its simple technique compared to other suture delivery systems.(2) F8 can be performed in a very short duration (30-60s), and its failure has been attributed to inadequate knot tie or suture break.(4, 6) Our study demonstrated on average a 21 minute reduction in the time needed to achieve satisfactory hemostasis when utilizing the F8 suture compared to traditional MC. Pracon et al., using doppler-duplex assessment of the groins, reported a slightly compressed mean vein diameter with the F8 stitch in place. This gives insight to the stitch's mechanism of action of utilizing the subcutaneous tissue pad to exert pressure on the puncture site. The pressure exerted by the compression is sufficient for hemostasis but maintains the vein's lumen dimensions. Venous thrombosis is a possible concern with a compressed vein diameter. Cilingiroglu et al demonstrated vasoconstriction at the sheath entry point through venography after F8 closure but vascular ultrasound following suture removal demonstrated resolution of the vasoconstriction along with femoral vein compressibility and the absence of thrombus. (1) Our study sought to determine and compare thromboembolic rates. Five of eight studies included thromboembolism as an outcome but no thromboembolic complications were observed aside from 2 events in the Issa 2015 MC arm, both of which were transient ischemic attacks.(4-6)

The use of F8 resulted in a 62% reduction in overall access site complications. The size of the sheaths used in the included studies varied widely, with reported sizes of up to 22 Fr, demonstrating safety and efficacy across a wide range of large venous sheath sizes. The reduction in access site complications may be explained by a shorter time to hemostasis in comparison to the MC group.

Although there were differences in procedural protocols in the included studies, we found a lower need for post-procedural protamine use in the F8 arm. This can lead to lower rates of thromboembolic complications and prevention of other commonly-reported side effects of protamine use such as anaphylaxis, hypotension and bradycardia.(23) Additional cost for suture material are lower in comparison to the amount saved from the use of protamine sulfate ($1.53 vs $7.60) (8)

Aside from outcomes reported in this study, Payne et al reported a reduced time to extubation and a reduced recovery time in the electrophysiology lab in their study with the use of F8 suture in comparison to MC. A subgroup analysis done in the study conducted by Jensen et al. showed a significantly higher rate of vascular complications in the manual compression arm (9.4% vs 0%; p= 0.045) in patients with obesity (body mass index [?]30 kg/m^2), a factor which should be considered in the decision to use MC. Of note, most of the studies included patients who underwent ablation for atrial fibrillation. The efficacy and safety of the F8 suture may possibly be greater in patients undergoing procedures which do not require continued anticoagulation.

5. Study Limitations

The following limitations should be considered in the interpretation of the results of this meta-analysis. Most of the studies included were observational. Some included studies were nonrandomized and retrospective in nature which may potentially have selection bias. A wide variety of venous sheaths sizes were used in the different studies. Although some studies reported utilizing sheaths < 8 Fr, procedural review showed that they were closed concomitantly with a bigger sheath size utilizing a single F8 suture. 4 studies did not monitor or report post-procedural thromboembolic complications. Included studies had variations in ablation protocols, protamine administration and timing of sheath removal. Publication bias is an inherent characteristic of any meta-analysis.

6. Conclusion

F8 is a safe and efficacious alternative to MC in large-bore venous access closure and its use results in a shortened time to hemostasis with a lower overall risk of access site complications and post-procedural protamine use. Further RCTs are needed to confirm these results.

TABLES AND FIGURES

Table 1 Study Characteristics

Study	Design	Total Patients	F8 arm Patients	Age FoE ± SD (years)	Male FoE	Mean CHADSVASC ± SD	Catheter Sizes Reported	Mean INR ± SD	Post-Procedural ACT (seconds) ± SD	Procedures Performed	Access Site Number	Access Sites Reported	Success Rate of FoE
Issa 2015	Retrospective observational	376	123	65.3 ± 12.0	60 (48.8%)	3.0 ± 1.7	9 Fr 11.5 Fr	2.6 ± 0.6	326 ± 57.0	Catheter Ablation of AF	4	Right and Left Femoral Vein	98.4%
Aytemir 2016	Prospective observational	200	100	55 ± 12.4	52 (52%)	NR	15 Fr	NR	NR	Cryoballoon-based AF ablation	1	Right femoral Vein	100%
Lakshmanadoss 2017	Retrospective observational	284	179	61.1±10.2	123 (68.7%)	1.9 ± 1.3	8.5 Fr	2.50 + 0.39	315 ± 58	Catheter ablation of AF	3	Right and Left Femoral Vein	100%
Akkaya 2017	Prospective observational	407	Radiofrequency Ablation (RF) group N=92 Cryoballoon Ablation(CB) N=96	RF 60 (58/63) CB 61 (59/63)	RF 55 (59.78%) CB 48 (50%)	RF 2 (2/2) CB 2 (1/2)	RF 9.5 Fr 11 Fr CB 14 Fr	RF 1.40 (1.32/1.47) CB 1.35 (1.27/1.42)	RF 319 (307/330) CB 306 (295/317)	Catheter ablation of AF Cryoballoon-based AF ablation	RF 4 CB 2	RF Right and Left Femoral Vein CB Right Femoral Vein	100%
Pracon 2018	Randomized controlled trial	90	60	59.9 ± 20.5	30%	NR	14 (IQR 13–14) Range 10-22 Fr	NR	NR	Left Atrial Appendage Occlusion Mitral Valve Commissurotomy ASD closure Pulmonary Valve Implantation Pulmonary Balloon Angioplasty	NR	Femoral Vein	91.7%
Okada 2018	Retrospective observational	517	270	63±11	218 (81)	NR	8 Fr 8.5 Fr	1.87± 0.74	325±34	Catheter ablation of atrial fibrillation	3	Right Femoral Vein	100%
Payne 2018	Retrospective observational	104	62	62.88 ± 10.73	45 (72.58%)	NR	8 Fr	1.4 ± 0.5	276.58 ± 35.21	Catheter ablation of atrial fibrillation	4	Right and Left Femoral Vein	100%
Kumar 2019	Randomized controlled trial	70	35	62.1 ± 9.5	21 (60%)	NR	9 Fr 11 Fr	NR	290 ± 73	Cryoballoon-based AF ablation	3.0 ± 1.0	Right and Left Femoral	100%

												Vein	
Jensen 2020	Prospective observational	290	158	66.4 ± 13.2	106 (67.1 %)	NR	14.8 ± 2.8 Fr	NR	NR	Pulmonary Vein Isolation Atrial Flutter Ablation Ablation of SVT VT Ablation Left Atrial Appendage Closure Patent Foramen Ovale Closure Electrophyisological Study	NR	Femoral Vein	98.7%

Figure 1 Figure of Eight Suture

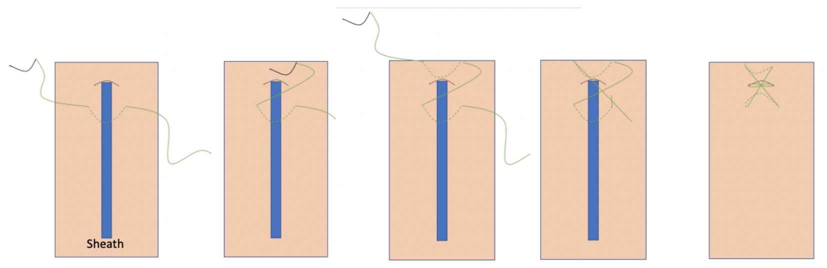
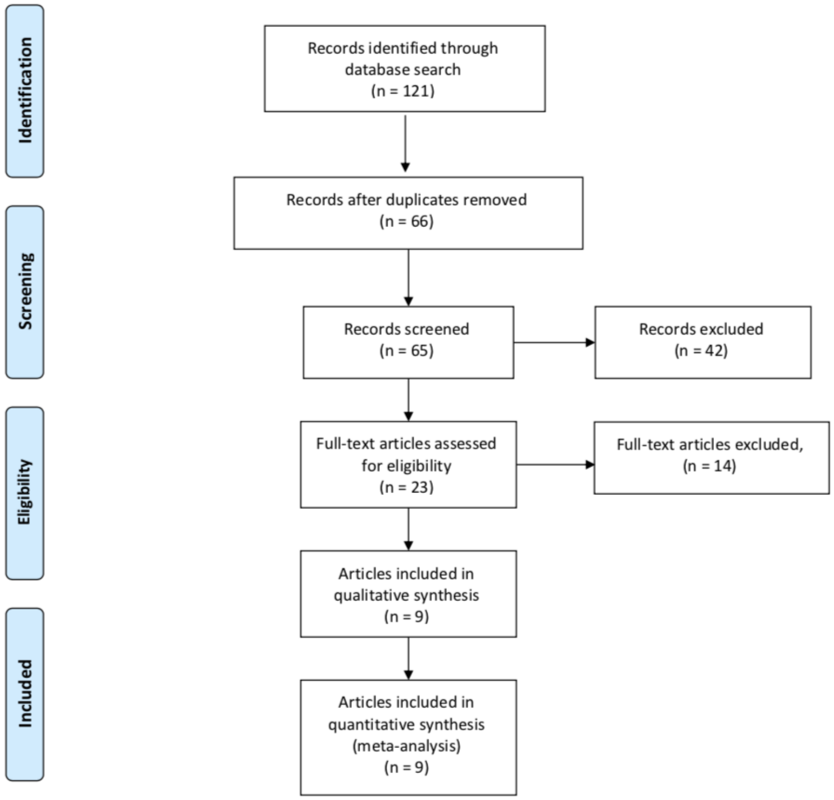


Figure 2 Prisma Flow Chart



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Figure 3.1 Overall time to achieve hemostasis

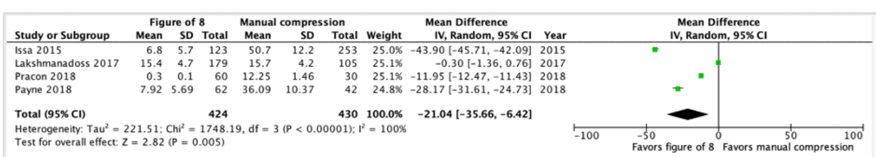


Figure 3.2 Overall access site complications

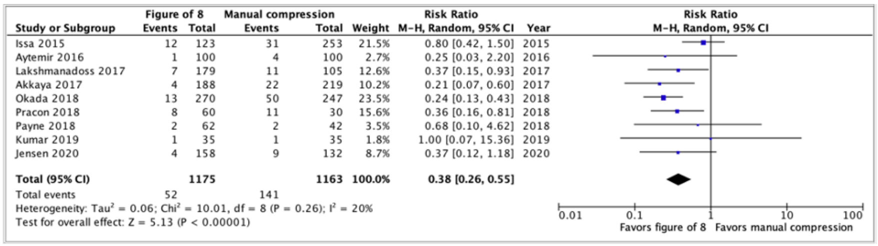


Figure 3.3 Access site complications for sheaths [?] 10 Fr

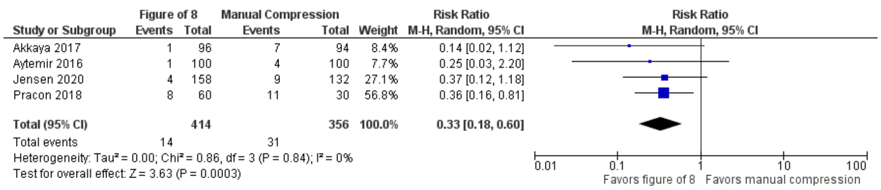


Figure 3.4 Fistula formation

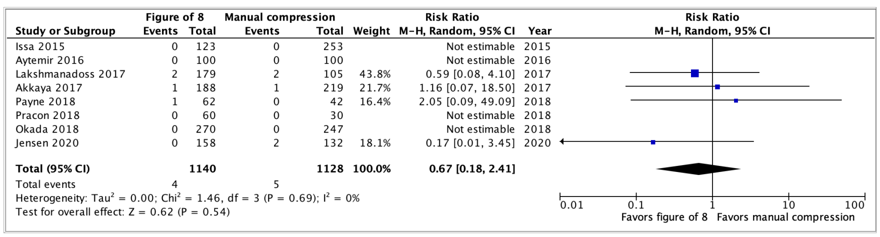


Figure 3.5 Pseudoaneurysm formation

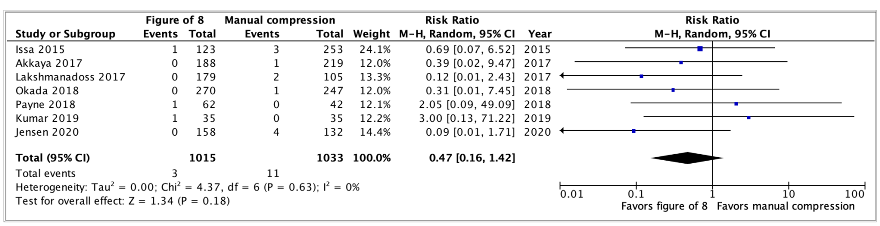


Figure 3.6 Access site hematoma

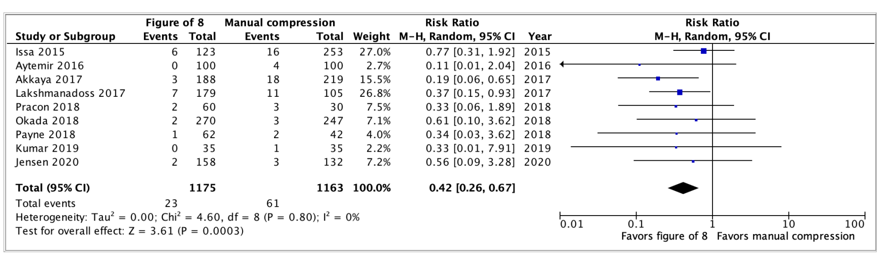


Figure 3.7 Access site bleeding

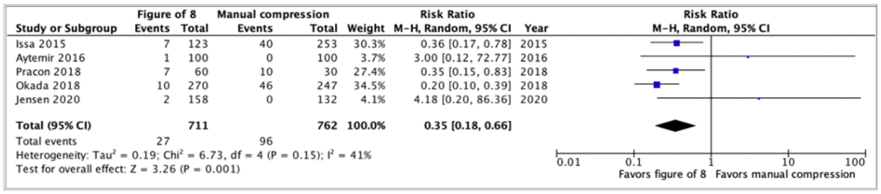
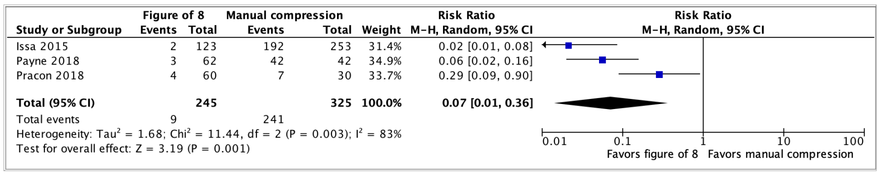


Figure 3.8 Post-procedural protamine use



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