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Review

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Prophylactic use of intravascular balloon occlusion in elective general non-cardiac surgery. Systematic review and meta-analysis of the literature

Uso profiláctico de balón de oclusión intravascular en cirugía general no cardiaca electiva. Revisión sistemática y metaanálisis de la literatura

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Keywords: intravascular balloon occlusion, hemorrhage, elective surgery.

Palabras clave: *balón de oclusión intravascular, hemorragia, cirugía electiva.*

ABSTRACT

Introduction: the use of endovascular occlusion balloon in elective non-cardiac surgery has emerged as an effective strategy to prevent intraoperative bleeding, a significant complication that can impact both surgical outcomes and patient recovery. This device, which selectively occludes large blood vessels, allows for precise control of blood flow, thereby minimizing the risk of hemorrhage and improving visibility in critical surgical areas. **Material and methods:** a search was performed across three major databases (PubMed, Ovid, and Embase), in addition to Google Scholar as a source of gray literature and the National Institute of Health (NIH) as a national database, covering the period from 2014 to 2024. **Results:** this systematic review included 17 articles; two showed a moderate risk of bias, while the others demonstrated good quality and low risk of bias. A total of 3,379 patients were analyzed, 95.3% women. The primary indication for the use of endovascular occlusion balloons was surgical procedures related to abnormal placentation in 67.5% of cases, with an average blood loss of 1,256 mL (SD: 699.9). The application of the balloon resulted in a significant reduction in blood loss of 856 mL (OR −3.43; 95% CI −6.22 to −0.63), with no significant differences observed in age, gender, or surgical duration. **Conclusion:** the use of intravascular balloon occlusion in elective non-cardiac general surgical procedures with a high risk of hemorrhage demonstrates effectiveness in reducing intraoperative blood loss. The most frequently observed complications include transient arterial thrombosis and localized issues at the puncture site. While various clinical scenarios for its application have been described, the strongest evidence supports its use in obstetric procedures, particularly those related to abnormal placentation.

RESUMEN

Introducción: *el uso de un balón de oclusión endovascular en cirugía electiva no cardiaca se ha revelado como una estrategia eficaz para prevenir las hemorragias intraoperatorias, una complicación importante que puede afectar tanto a los resultados quirúrgicos como a la recuperación del paciente. Este dispositivo, que ocluye selectivamente grandes vasos sanguíneos, permite un control preciso del flujo sanguíneo, minimizando así el riesgo de hemorragia y mejorando la visibilidad en zonas quirúrgicas críticas.* ***Material y métodos:*** *se realizó una búsqueda en tres bases de datos principales (PubMed, Ovid y Embase), además de Google Scholar como fuente de literatura gris y el Instituto Nacional de Salud (NIH) como base de datos nacional, abarcando el periodo de 2014 a 2024.* ***Resultados:*** *esta revisión sistemática incluyó 17 artículos; dos mostraron un riesgo moderado de sesgo, mientras que los demás demostraron buena calidad y bajo riesgo de sesgo. Se analizaron un total de 3,379 pacientes, de los cuales 95.3% fueron mujeres. La principal indicación para el uso de balones de oclusión endovascular fueron procedimientos quirúrgicos relacionados con la placentación anormal en 67.5% de los casos, con una pérdida sanguínea promedio de 1,256 mL (DE: 699.9). La aplicación del balón resultó en una reducción significativa de la pérdida de sangre de 856 mL (OR −3.43; IC95% −6.22 a −0.63), sin diferencias significativas observadas en edad, género o duración quirúrgica.* ***Conclusión:*** *el uso de oclusión con balón intravascular en procedimientos quirúrgicos generales electivos no cardiacos con alto riesgo de hemorragia demuestra efectividad en la reducción de la pérdida de sangre intraoperatoria. Las complicaciones más frecuentemente observadas incluyen trombosis arterial transitoria y problemas localizados en el sitio de punción. Aunque se han descrito diversos escenarios clínicos para su aplicación, la evidencia más sólida apoya su uso en procedimientos obstétricos, particularmente aquellos relacionados con la placentación anormal.*

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INTRODUCTION

The endovascular balloon occlusion is a method that has been introduced as a concept for more than 70 years, a result of the Korean War,[1] and since then, it has been put into sequential study and applied in the context of patient victims of military traumatic injuries and civilians. This has advanced to the point of becoming an endovascular technique that is easily applicable in the emergency department and in surgery rooms.[2] However, in search of making better use of this resource, in recent years, the concept of intravascular occlusion in the arterial and/or venous system has been applied in elective surgery as a complement in the treatment of various medical-surgical conditions in search of explored new strategies to prevent and control intra- and postoperative hemorrhagic events.

Historically, one of the main and most feared complications related to fatal outcomes is massive bleeding and secondary hypovolemic shock. Numerous efforts have been directed towards creating devices and interventional techniques to reduce or even prevent bleeding. Since its first application by Hughes on two wounded soldiers in the Korean War,[1] large blood vessel endovascular occlusion devices have opened multiple doors, leading to two main objectives. The first is bleeding control, such as in cases of severe trauma associated with non-compressible bleeding, ruptured abdominal aortic aneurysms, postpartum hemorrhage, etc., where the goal is to control an already established hemorrhage.[3] The second is the prevention of bleeding, which is the focus of more recent research, implementing these devices in elective (non-urgent) pelvic-obstetric, renal, hepatobiliary, and gastrointestinal procedures to avoid hemorrhage and its associated complications.

Effective management of intraoperative bleeding is essential for the success of any surgical procedure and remains a significant concern worldwide and locally, as hemorrhagic complications continue to impact the outcomes of certain types of procedures negatively, increasing reinterventions, massive transfusions, organ or multi-organ dysfunction, and in some situations, even death.[4]

In recent decades, technological advancements have led to the development of innovative endovascular techniques and devices to control hemorrhage during surgery. One of these significant advancements has been the introduction and use of intravascular occlusion balloons in adult patients undergoing elective surgery.[3,4] Initially, these devices were used in the trauma context to control massive bleeding, either through open or closed methods, but their application has expanded to non-traumatized adult patients undergoing major elective surgical procedures with significant bleeding risk.[5]

The implementation of these occlusion devices at the aortic and vena cava levels has demonstrated substantial benefits in terms of improved survival rates and fewer post-surgical hemorrhagic complications in patients who have experienced open or closed accidents.[6,7] This initial success has led to the exploration of their preventive use in elective surgeries, where a high risk of potentially fatal intraoperative bleeding is anticipated.[8]

Despite the growing popularity of this technique and several isolated studies, there is little evidence in the scientific literature regarding its indications, efficacy, safety, impact on the magnitude of bleeding, blood component polytransfusion, and mortality in the context of elective surgeries. Moreover, its current use is justified by isolated studies with diverse methodologies and results, often based on local experiences. Therefore, it is crucial to address this knowledge gap in an organized and systematic manner so that the available data can be collected, analyzed, and interpreted, and based on this, establish guidelines based on the best evidence to optimize bleeding outcomes for patients undergoing elective surgical procedures.

This systematic literature review aims to provide a specific response by thoroughly evaluating existing studies on the use of intravascular occlusion balloons in elective surgeries concerning the amount of intraoperative bleeding. By doing so, it seeks to provide a more synthesized and concrete view of the actual effectiveness of this technique in the context of non-traumatic surgical procedures based on the literature available to date.

The results of this review could have significant implications for clinical practice. If intravascular occlusion balloons are confirmed to be effective in reducing intraoperative bleeding in elective surgeries, this could support their prophylactic use and lead to a substantial reduction in bleeding-related complications. Additionally, by providing evidence-based guidance, this review can serve as a foundation for developing local, national, and international clinical protocols and help scientific communities generate recommendations on the implementation of this technique.

MATERIAL AND METHODS

Methodology

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.[9]

The inclusion criteria for the review encompassed studies involving adult patients over 18 years of age undergoing elective surgery where intravascular occlusion balloons were used. The types of interventions considered included intravascular occlusion with arterial or venous balloons in elective surgery. The primary outcome of interest was the amount of intraoperative hemorrhage when intravascular balloon occlusion was utilized. Eligible studies included observational, analytical, and descriptive types and only those reported in English and Spanish were considered.

The exclusion criteria for the review included studies carried out in animal models or species other than humans, as well as those focused on emergency surgery. Studies were also excluded if they used devices other than intravascular, temporary, or definitive occlusion balloons in elective surgery or if they presented unrelated results that did not provide relevant and clear information on the reduction of intraoperative hemorrhage with intravascular occlusion balloons. Duplicate studies were excluded, retaining only the most complete and detailed version. Additionally, publications not subject to review by both researchers were excluded.

The search was carried out in three main databases: PubMed, Ovid, Embase, and Google Scholar, which is a gray literature database, and the National Institute of Health (INS) as a national database. Articles written in English and/or Spanish were accepted and published in the last 10 years until April 2024. The search result was stored in Mendeley and Rayyan© as organizer and reference manager, respectively. Additionally, bibliographic references of the included studies were searched and compiled to ensure a comprehensive review of the literature.

The searches were executed with the keywords in terms Mesh (Medical Subject Headings) Thesaurus on the health sciences of the National Library of Medicine (NLM); Vena Cava, Superior, Vena Cava, Inferior, Aorta, Aorta, Thoracic, Aorta, Abdominal, Balloon Occlusion, Wounds, and Injuries. Once these Mesh terms were set, the Boolean operators were used as follows: (((Vena Cava, Superior[Mesh] OR Vena Cava, Inferior[Mesh]) OR (Aorta"[Mesh] OR Aorta, Thoracic[Mesh] OR Aorta, Abdominal[Mesh])) AND Balloon Occlusion[Mesh]) NOT Wounds and Injuries[Mesh]. Duplicate studies were removed using the Rayyan tool.

Study selection

Each author independently reviewed the titles and abstracts of the articles in the database obtained as a result of the search strategy; Articles that were not related to the research question were excluded. Full texts were obtained only from articles considered potentially eligible by at least one reviewer. Subsequently, each author independently reviewed the full texts of the potentially eligible articles, verified the inclusion and exclusion criteria, and established the definitive articles for carrying out the present systematic review. Cases where there was a discrepancy were resolved by consensus in the first instance, and if disagreement persisted, a third reviewer determined whether or not to include the article.

Data extraction process

For data extraction, the artificial intelligence tool SciSpace[10] was used as the first instance, where the articles included in the study

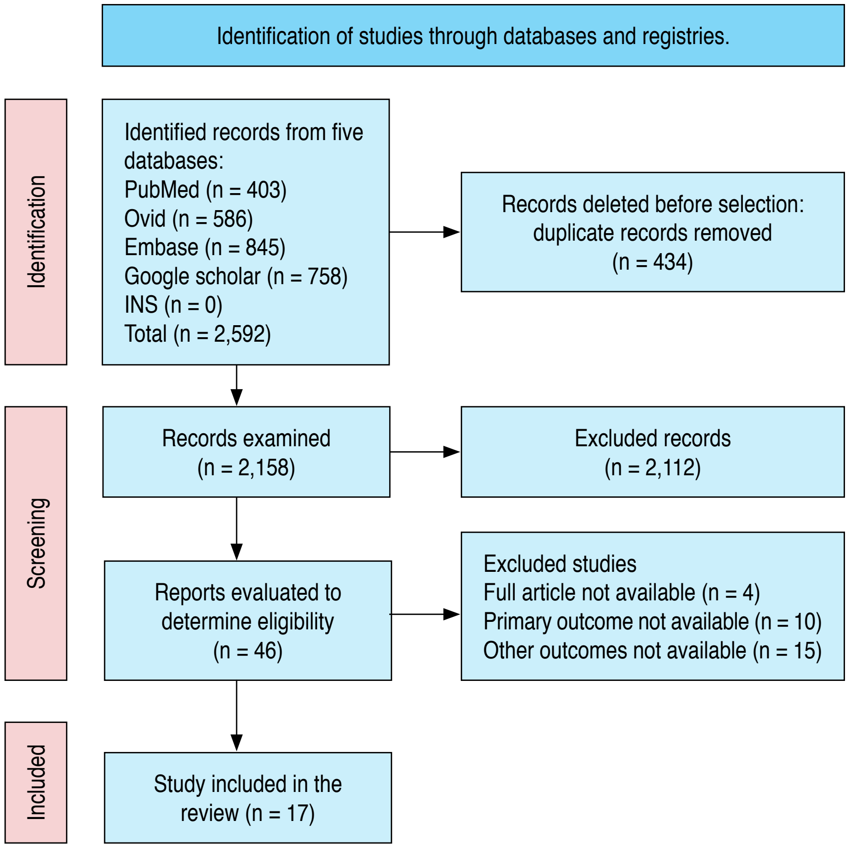


Figure 1:

PRISMA diagram.

were entered and the specific data were screened. The information collected from each article included authors, year of publication, study design, number of participants in the intervention group and control group, indication for intravascular occlusion, site of vascular occlusion, amount of bleeding during the intervention, surgical time, and complications associated with the intervention. Additionally, for some numerical variables, dispersion measures such as the mean and standard deviation were recorded. In cases where automatic extraction of information was not obtained, it was added manually. Subsequently, each author independently corroborated the veracity of the information collected.

The data obtained were tabulated in a standardized Excel spreadsheet (Microsoft). Finally, articles that did not provide the total of the mentioned variables were excluded in order to avoid bias in obtaining results and analyzing them.

Risk of bias and quality of included studies

The Newcastle-Ottawa scale was used to assess the risk of bias, a validated and widely used instrument to evaluate the risk of bias in observational studies.[11] This scale considers three domains: selection of participants, comparability between groups, and evaluation of exposure or results.[12] Methodological quality was classified according to the following criteria: (a) Good: three to four stars in selection, one to two in comparability, and two to three in results/exposition; (b) Fair: two stars in selection, one to two in comparability and two to three in results/exhibition; (c): zero to one star for selection, zero for comparability and zero to one for results/exhibition.[11]

Statistical analysis

Data analysis and management were carried out using STATA statistical software. For the qualitative variables, the log Odds ratio method was used, with a random effects model to calculate the Odds Ratio (OR) and the 95% confidence interval (95% CI). For numerical variables, the inverse variance method with a random effects model was used to determine the standardized mean difference (SMD) with its 95% CI. The presence of statistical heterogeneity was evaluated using the I^2 test to measure the magnitude of heterogeneity; statistical heterogeneity was considered a value greater than 50%.

RESULTS

After applying the search strategy across all databases, we obtained a total of 2,592 articles, distributed as follows: PubMed (n = 403), EMBASE (n = 845), OVID (n = 585), Google Scholar (n = 758), and INS (n = 0). Ultimately, we included 17 articles in the systematic review, excluding the remaining publications through a rigorous screening process *(Figure 1)*.

Our analysis revealed no randomized controlled trials regarding occlusion balloons in elective surgery. Among the 17 included studies, 10 were retrospective cohorts,[13-22] one was a prospective cohort study,[23] and six were case-control studies.[24-29] We assessed the quality and risk of bias of all studies using the Newcastle-Ottawa Scale for cohorts and case-control studies, focusing on selection, comparability, and outcomes. Two retrospective cohorts exhibited a moderate risk of bias, while the remaining articles demonstrated good quality and low risk of bias *(Table 1)*.

This review included a total of 3,379 patients, comprising 157 men (4.7%) and 3,222 women (95.3%). The average age in the intervention group was 36.4 years (SD: 5.9), compared to 37.0 years (SD: 6.1) in the non-intervention group *(Table 2)*.

The conditions for which intravascular occlusion balloons were utilized in elective surgical treatments included abnormal placentation (placenta accreta) in 2,281

Table 1: Results of quality assessment using the Newcastle-Ottawa scale for all studies.

Study	Type of study	Selection	Comparability	Exposure or results	Methodological quality
Ioscovich A (2023)	Cases and controls	4	2	3	Good
Hao Z (2016)	Cases and controls	4	1	3	Good
Zeng C (2017)	Cases and controls	3	1	1	Regular
Filho S (2019)	Retrospective cohort	4	1	3	Good
Huo F (2021)	Retrospective cohort	4	1	2	Good
Kaneda H (2017)	Cases and controls	4	1	2	Good
Kyozuka H (2023)	Retrospective cohort	4	1	3	Good
Papillon-Smith J (2020)	Retrospective cohort	4	1	3	Good
Ye Y (2023)	Retrospective cohort	4	1	3	Good
Wu Q (2016)	Retrospective cohort	4	1	3	Good
Peng W (2020)	Retrospective cohort	2	1	2	Regular
Zhao X (2016)	Cases and controls	4	2	2	Good
Duan X (2018)	Retrospective cohort	3	1	2	Good
Wang Y (2020)	Retrospective cohort	4	1	3	Good
Peng Y (2020)	Cases and controls	4	2	3	Good
Zhao Z (2020)	Prospective cohort	3	1	2	Good
Zangh Y (2018)	Retrospective cohort	4	1	3	Good

Good: 3 to 4 stars for selection, 1 to 2 for comparability, and 2 to 3 for results/exhibition; Fair: 2 stars in selection, 1 to 2 in comparability and 2 to 3 in results/exhibition; Bad: 0 to 1 on selection, 0 on comparability and 0 to 1 on results/exposure.

Table 2: Comparative outcomes in groups studied with respect to age, indication and site of occlusion.

		Intervention group (ball)				Non-intervention group (no ball)					
			Gender		Age (years)		Gender		Age (years)		
Study	Patients	n	H	M	Mean ± SD	n	H	M	Mean ± SD	Indication	Occlusion site
Ioscovich A 2023	21	10	0	10	35 ± 5.02	11	0	11	33.8 ± 4.5	Abnormal placentation	Infrarenal abdominal aorta
Hao Z 2016	41	18	11	7	34.2 ± 2.5	23	14	9	34 ± 2.1	Complex acetabular fracture	Infrarenal abdominal aorta
Zeng C 2017	86	48	0	48	32.3 ± 5.27	38	0	38	33.1 ± 5.23	Abnormal placentation	Infrarenal abdominal aorta
Filho S 2019	35	28	0	28	33 (24-43)*	7	-	-	-	Abnormal placentation	Bilateral internal iliac artery
Huo F 2021	33	17	0	17	32.82 ± 4.45	16	0	16	34.44 ± 4.79	Abnormal placentation	Infrarenal abdominal aorta
Kaneda H 2017	518 (Hysterectomy)	12	0	12	49.5 (36-62)*	506	0	506	47 (34-69)*	Large uterine cervical fibroid	Bilateral internal iliac artery
	305 (Miomectomy)	10	0	10	35.5 (28-40)*	295	0	295	38 (23-63)*		
Kyozuka H 2023	37	13	0	13	37.5 (30.8-41)*	24	0	24	35 (32-38)*	Abnormal placentation	Supraceliac Aorta
Papillon-Smith J 2020	79	47	0	47	35 (22-51)*	32	0	32	34 (25-44*)	Abnormal placentation	Internal iliac artery
Ye Y 2023	364	278	0	278	34 (30-37)*	86	0	86	34 (32-36)*	Abnormal placentation	Infrarenal abdominal aorta
Wu Q 2016	268	230	0	230	29.5 ± 3.6	38	0	38	30.4 ± 4	Abnormal placentation	Infrarenal abdominal aorta
Peng W 2020	586	252	0	252	32.69 ± 4.62	296	0	296	32.74 ± 4.84	Abnormal placentation	Infrarenal abdominal aorta
Zhao X 2016	57	23	13	10	44.36 ± 13.34	34	15	19	45.41 ± 15.7	Pelvic or hip tumor resection	Infrarenal abdominal aorta
Duan X 2018	45	22	0	22	32,1 ± 6.9	23	0	23	31.7 ± 8.5	Abnormal placentation	Infrarenal abdominal aorta
Wang Y 2020	623	623	0	623	-	23	0	-	-	Abnormal placentation	Infrarenal abdominal aorta
Peng Y 2020	104	48	0	48	32.08 ± 3.94	56	0	48	33.46 ± 4.53	Abnormal placentation	Bilateral internal iliac artery
Zhao Z 2020	121	57	33	24	48 (18-70)*	64	34	30	45 (18-70)*	Pelvic or hip tumor resection	Infrarenal abdominal aorta
Zangh Y 2018	56	30	20	10	42 ± 18	26	17	9	50 ± 19	Pelvic or hip tumor resection	Infrarenal abdominal aorta

* Median and (range)
SD = Standard deviation.

patients (67.5%), giant cervical uterine fibroids in 823 patients (24.3%), resection of sacrococcygeal tumors in 234 patients (6.9%), and open reduction and internal fixation of complex acetabular fractures in 41 patients (1.2%) *(Table 2)*.

The anatomical sites selected for endovascular balloon occlusion were infrarenal abdominal aorta in 68% (n = 2,301), bilateral internal iliac arteries in 30.8% (n = 1,041), and suprarenal aorta in 1.09% (n = 37).

Regarding intraoperative bleeding, the intervention group (endovascular occlusion balloon use) had an average blood loss of 1,256 mL (SD: 669.9), while the non-intervention group (no balloon use) reported an average blood loss of 2,112 mL (SD: 1,027.8) *(Table 3)*.

Table 4: Intervention group with respect to complications.

Complication	n (%)
Arterial thromboembolism	79 (53.00)
Emergency hysterectomy	45 (30.20)
Skin lesions or local hematoma	12 (8.05)
Vasospasm	5 (3.35)
Femoral pseudoaneurysm	2 (1.34)
Balloon dysfunction	2 (1.34)
Femoral nerve injury	1 (0.67)
Arteriovenous fistula	1 (0.67)
Operative site infection	1 (0.67)
Arterial dissection	1 (0.67)
Total	149 (100.00)

Table 3: Comparative outcomes in groups studied with respect to amount of bleeding.

	Intervention group (ball)				Non-intervention group (no ball)			
	Bleeding (mL)		Time (min)		Bleeding (mL)		Time (min)	
Study	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Ioscovich A 2023	1,060	296.64	119	29.41	4,400	2,787	149.81	47.69
Hao Z 2016	1,247.2	67.1	213.3	8.9	1,526.1	69.9	248.30	7.00
Zeng C 2017	1,467.71	1,075.77	92.19	32.5	2,218.42	1,572.2	119.47	59.37
Filho S 2019	1,193	679	332	70	2,273.4	–	–	–
Huo F 2021	3,167.65	3,255.71	–	–	2,831.25	1,906.03	–	–
Kaneda H 2017	510	–	178	116-300*	350	–	165.50	57-686
	727.5	–	157.5	156-218*	390	–	160	52-366*
Kyozuka H 2023	1,110	–	144	112-163*	2,160	–	146	126-164*
Papillon-Smith J 2020	1,713	181	353	14.00	1,874	245	227	13.00
Ye Y 2023	1,370.5	752	96.3	37.6	3,536.8	1,383.2	160.60	45.50
Wu Q 2016	921	199	64.1	5.1	2,790	335	92.10	9.70
Peng W 2020	1,967.66	1,466.64	191.05	59.4	1,338.18	1,286.14	153.02	57.33
Zhao X 2016	437.23	54.32	193.28	63.47	1,846.45	87.56	273.63	73.31
Duan X 2018	597	359	63.8	12.3	2,687	575	118.80	22.40
Wang Y 2020	620	570	65.3	14.5	2,687	575	–	–
Peng Y 2020	1,504.17	1,123.44	158.44	57.32	1,108.04	1,008.32	104.20	46.22
Zhao Z 2020	1,000	–	185	100-500*	1,350	–	260	180-600*
Zangh Y 2018	2,000	–	215	110-430*	2,650	–	225	115-340*

* Range.
SD = Standard deviation.

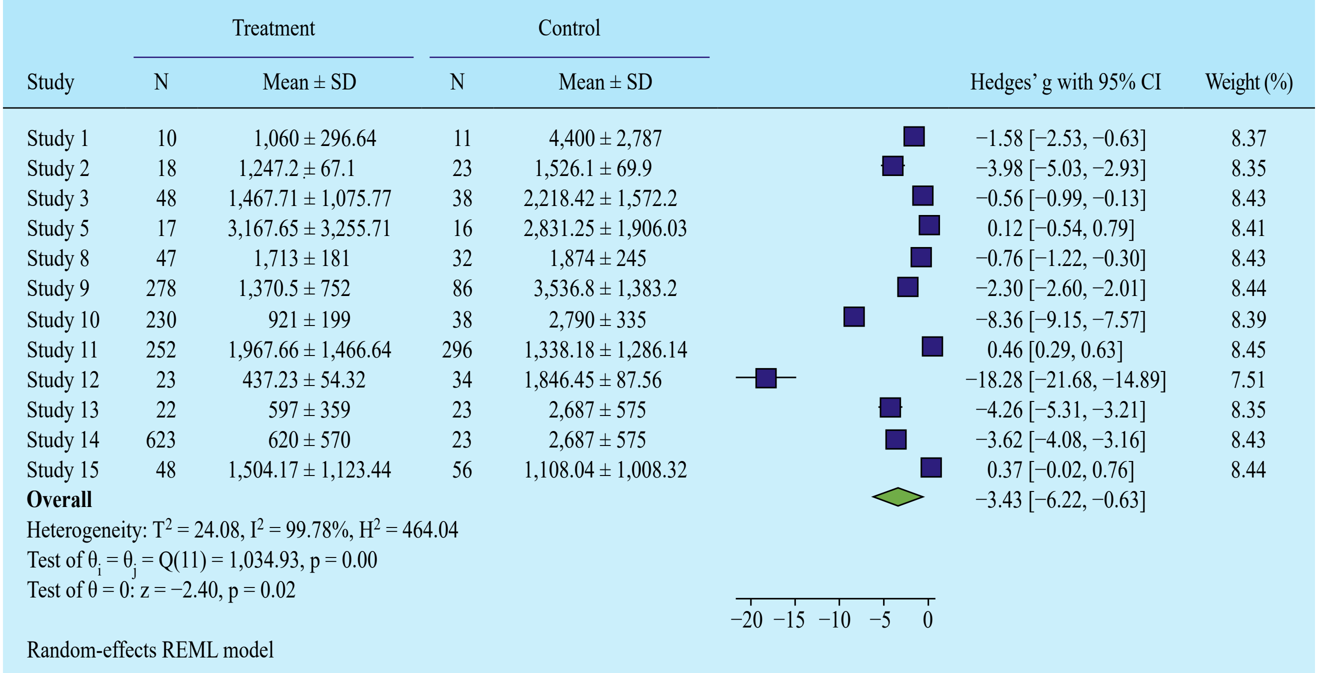


Figure 2: Forest Plot. Statistical analysis of intraoperative bleeding variables.

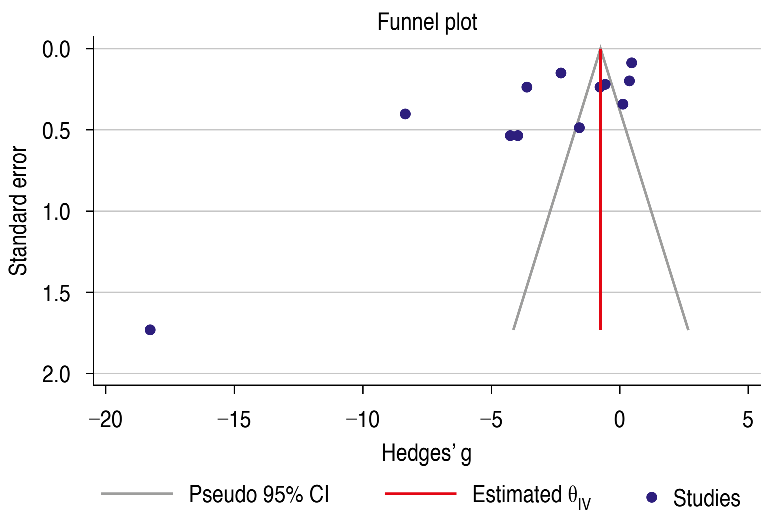


Figure 3: Funnel Plot. Statistical analysis of intraoperative bleeding variables.

Surgical duration also constituted a measured outcome in this study. In the intervention group, the average duration of surgical procedures was 165.9 minutes (SD: 84), while in the non-intervention group, it was 173.5 minutes (SD: 58.6).

A total of 149 participants (4.4% of the total included) experienced complications related to the use of the endovascular occlusion balloon. These included 79 arterial thromboembolic events, 45 emergency hysterectomies due to uncontrolled bleeding, 12 cases of skin and subcutaneous tissue injuries or local hematomas, five cases of vasospasm, two pseudoaneurysms of femoral vessels, and two cases related to balloon issues (migration and rupture). Other less frequent complications included femoral nerve injury, arteriovenous fistula, surgical site infection, and femoral artery dissection (one case each). Five studies reported no complications *(Table 4)*.

Quantitative Analysis

The systematic review (meta-analysis) was performed on 17 studies encompassing a total of 3,379 patients. The following variables were analyzed in the meta-analysis.

Intraoperative Bleeding

In this outcome, only 12 studies were subjected to statistical analysis *(Table 5)*, revealing that the intervention serves as a protective factor against bleeding, with an odds ratio (OR) of −3.43 (95% CI −6.22; −0.63). The overall analysis exhibited high statistical heterogeneity (I^2 of 99.7%) with a significant p-value *(Figure 2)*.

The general asymmetry of the funnel plot for this variable suggests significant publication bias. However, the dispersion observed in smaller studies may indicate heterogeneity among them *(Figure 3)*.

The lack of alignment of most studies along the regression line suggests general disparity in the meta-analysis results, characterized by marked heterogeneity *(Figure 4)*.

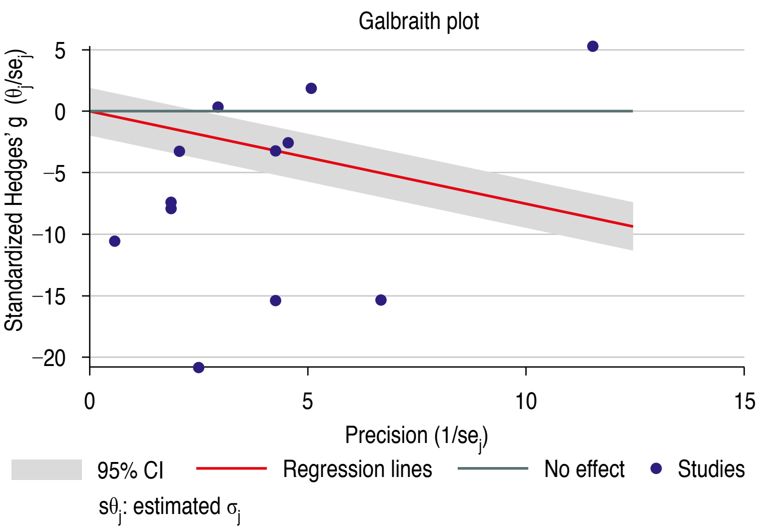


Figure 4: Galbraith Plot. Statistical analysis of intraoperative bleeding variables.

Gender

No significant differences were found, with an OR of 0.19 (95% CI −0.26; 0.64), and no statistical heterogeneity was observed (I^2 of 0%) *(Figure 5)*.

Age

No significant differences were identified with respect to age, with an OR of 0.06 (95% CI −0.15; 0.04), and no statistical heterogeneity

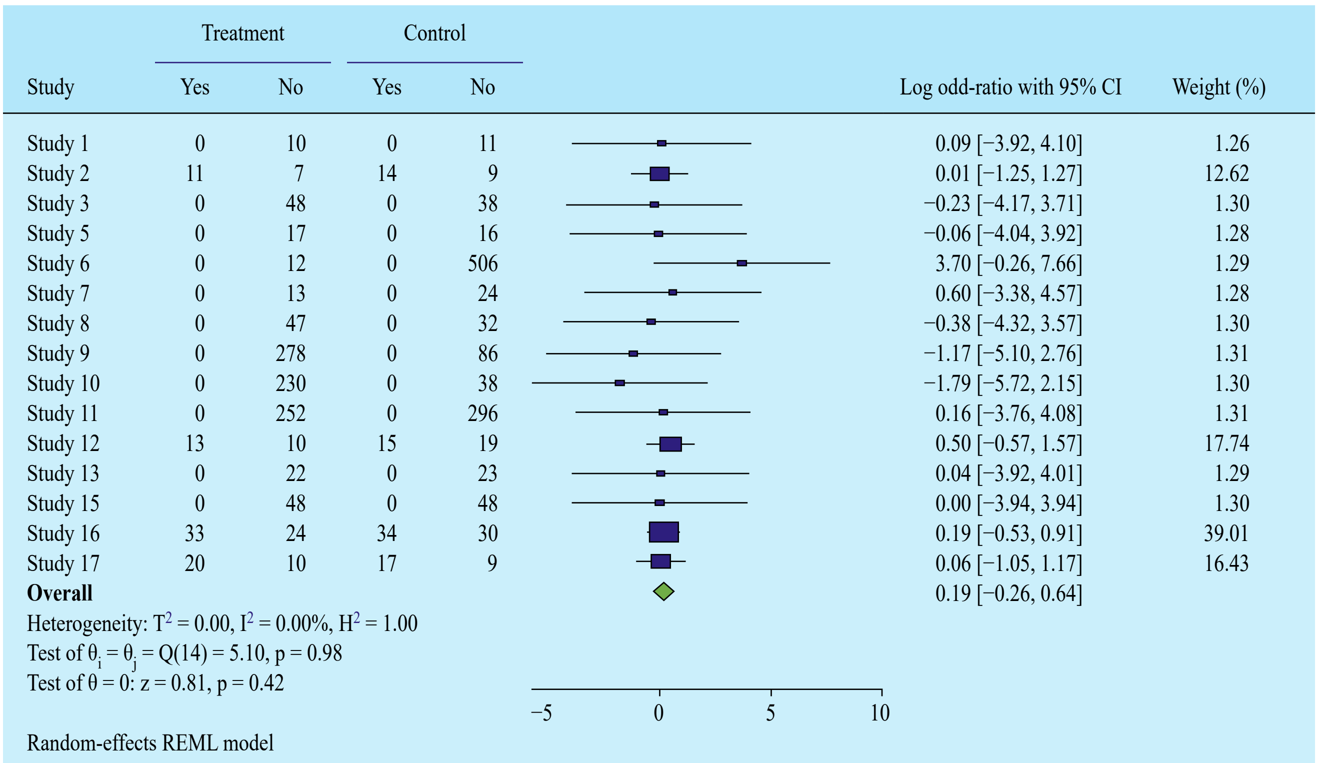
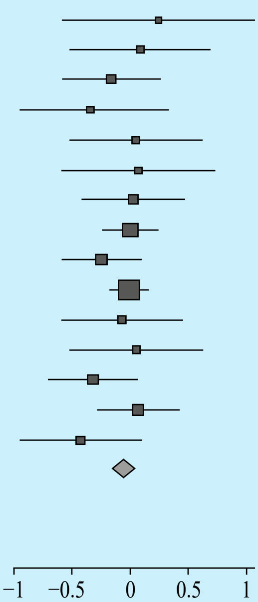


Figure 5: Forest Plot. Statistical analysis of gender variables. (Yes: men; No: Women).



Study	Treatment N	Treatment Mean ± SD	Control N	Control Mean ± SD	Log odd-ratio with 95% CI	Weight (%)
Study 1	10	35 ± 5.019	11	33.8 ± 4.5	0.24 [−0.58, 1.07]	1.35
Study 2	18	34.2 ± 2.5	23	34 ± 2.1	0.09 [−0.52, 0.69]	2.51
Study 3	48	32.27 ± 5.27	38	33.13 ± 5.23	−0.16 [−0.58, 0.26]	5.16
Study 5	17	32.82 ± 4.45	16	34.44 ± 4.79	−0.34 [−1.01, 0.33]	2.04
Study 6	12	49.5 ± 49	506	47 ± 51.5	0.05 [−0.52, 0.62]	2.82
Study 7	13	37.5 ± 35.45	24	35 ± 35	0.07 [−0.59, 0.73]	2.11
Study 8	47	35 ± 36.5	32	34 ± 34.5	0.03 [−0.42. 0.47]	4.65
Study 9	278	34 ± 33.5	86	34 ± 34	0.00 [−0.24, 0.24]	15.80
Study 10	230	29.5 ± 3.6	38	30.4 ± 4	−0.25 [−0.59, 0.10]	7.83
Study 11	252	32.69 ± 4.62	296	32.74 ± 4.84	−0.01 [−0.18, 0.16]	32.70
Study 12	23	44.36 ± 13.34	34	45.41 ± 15.77	−0.07 [−0.59, 0.45]	3.38
Study 13	22	32.1 ± 6.9	23	31.7 ± 8.5	0.05 [−0.52, 0.62]	2.79
Study 15	48	32.08 ± 3.94	56	33.46 ± 4.53	−0.32 [−0.71, 0.06]	6.20
Study 16	57	48 ± 44	64	45 ± 44	0.07 [−0.29, 0.42]	7.31
Study 17	30	42 ± 18	26	50 ± 19	−0.43 [−0.95, 0.10]	3.35
Overall					−0.06 [−0.15, 0.04]	

Heterogeneity: $T^2 = 0.00$, $I^2 = 0.00\%$, $H^2 = 1.00$

Test of $\theta_i = \theta_j$ = Q(14) = 8.06, p = 0.89

Test of $\theta = 0$: z = −1.20, p = 0.23

Random-effects REML model

Figure 6: Forest Plot. Statistical analysis of age variables.

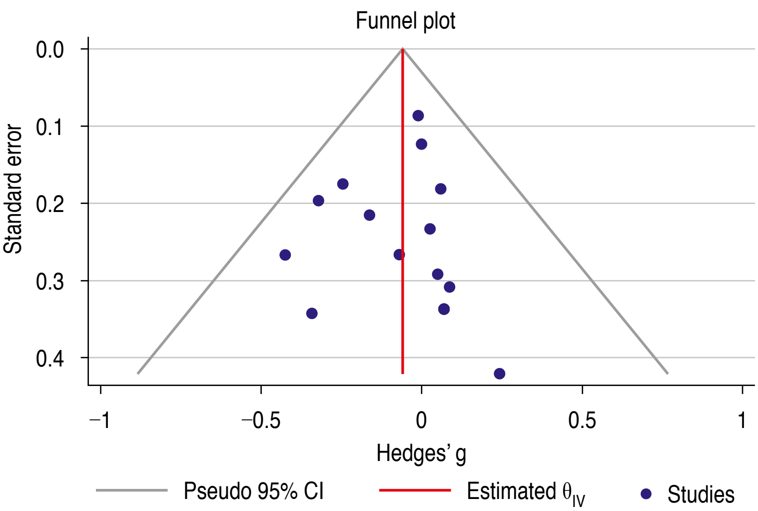


Figure 7: Funnel Plot. Statistical analysis of age variables.

was observed (I^2 of 0%) *(Figure 6)*. The general symmetry of the funnel plot suggests an absence of relevant publication bias. However, the slight dispersion observed in smaller studies may indicate some heterogeneity, warranting further exploration to identify potential differences in study designs or populations *(Figure 7)*. The alignment of most studies along the regression line indicates overall consistency in the meta-analysis results, with limited heterogeneity and no outlier studies contributing to the overall heterogeneity *(Figure 8)*.

Surgical duration

No significant differences were found in terms of duration reduction, with an OR of −0.47 (95% CI −2.13; 1.18), and statistical heterogeneity was observed (I^2 of 99.5%) *(Figure 9)*. The overall asymmetry of the funnel plot for this variable suggests significant publication bias. However, the dispersion in smaller studies may indicate heterogeneity among them *(Figure 10)*. The lack of alignment of most studies along the regression line suggests general disparity in the meta-analysis results, characterized by marked heterogeneity *(Figure 11)*.

DISCUSSION

Our results indicate that certain sociodemographic variables, such as female gender and age, characterize the population in which the intravascular balloon occlusion technique is most frequently applied. These findings align with the observational study by Wang Y,[21] which included approximately 623 female patients, and the study by Peng W[19] with 296 female patients. Both studies were conducted by gynecology groups focusing on abnormal placentation pathologies. Age, as an isolated variable, is supported by studies from Ye Y,[17] Wu Q,[18] Peng W,[19] and Wang Y,[21] which suggest that abnormal placentation is more prevalent among young women of reproductive age, typically under 40 years.

The pathology most frequently addressed using this technique was abnormal placentation, corroborated by studies such as those by Peng W[19] and Ye Y.[17] This was followed by the presence of giant fibroids, as highlighted in Kaneda H's study,[27] which reported the largest patient cohorts and emphasized the technique's role in reducing morbidity and mortality. Notably, the third most common pathology was non-gynecological in nature,

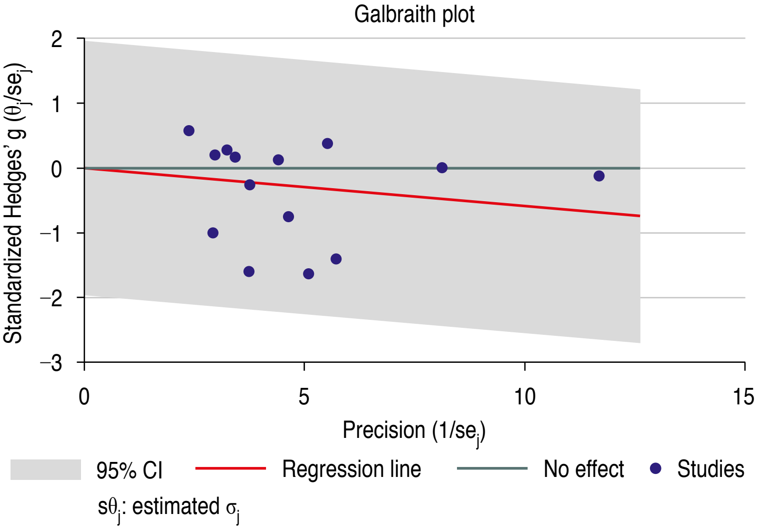
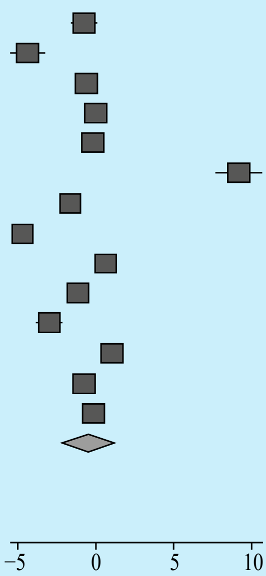


Figure 8: Galbraith Plot. Statistical analysis of age variables.

Study	Treatment N	Treatment Mean ± SD	Control N	Control Mean ± SD	Log odd-ratio with 95% CI	Weight (%)
Study 1	10	119 ± 29.41	11	149.81 ± 47.69	−0.74 [−1.59, 0.11]	7.10
Study 2	18	213.3 ± 8.9	23	248.3 ± 7.0	−4.35 [−5.47, −3.23]	7.01
Study 3	48	92.19 ± 32.5	38	119.47 ± 59.37	−0.58 [−1.01, −0.15]	7.20
Study 6	12	178 ± 46	506	165.5 ± 671.75	0.02 [−0.55, 0.59]	7.18
Study 7	13	144 ± 12.75	24	146 ± 9.5	−0.18 [−0.84, 0.48]	7.15
Study 8	47	353 ± 14	32	227 ± 13	9.17 [7.67, 10.67]	6.83
Study 9	278	96.3 ± 37.6	86	160.6 ± 45.5	−1.62 [−1.89, −1.35]	7.22
Study 10	230	64.1 ± 5.1	38	92.1 ± 9.7	−4.69 [−5.21, −4.16]	7.19
Study 11	252	191.05 ± 59.4	296	153.02 ± 57.33	0.65 [0.48, 0.82]	7.23
Study 12	23	193.28 ± 63.47	34	273.63 ± 73.31	−1.14 [−1.70, −0.58]	7.18
Study 13	22	63.8 ± 12.3	23	118.8 ± 22.4	−2.97 [−3.81, −2.13]	7.10
Study 15	48	158.44 ± 57.32	56	104.2 ± 46.22	1.04 [0.63, 1.45]	7.21
Study 16	57	185 ± 100	64	260 ± 105	−0.73 [−1.09, −0.36]	7.21
Study 17	30	215 ± 80	26	225 ± 56.25	−0.14 [−0.66, 0.38]	7.19
Overall					−0.47 [−2.13, 1.18]	

Heterogeneity: $T^2 = 9.85$, $I^2 = 99.50\%$, $H^2 = 201.55$
Test of $\theta_i = \theta_j$ = Q(13) = 781.65, p = 0.00
Test of $\theta = 0$: z = −0.56, p = 0.58



Random-effects REML model

Figure 9: Forest Plot. Statistical analysis of surgical time variables.

specifically the open reduction of long bone fractures in the lower extremities, as reported by Hao Z.[25] This study also included the highest number of male patients in our review.

Regarding the occlusion sites, all procedures were performed within the arterial system, primarily at the infrarenal aorta. In two studies, Kaneda H[27] and Peng W,[19] occlusions were performed as distally as possible, bilaterally at the internal iliac arteries. These findings correspond with studies that had the largest patient populations and most representative

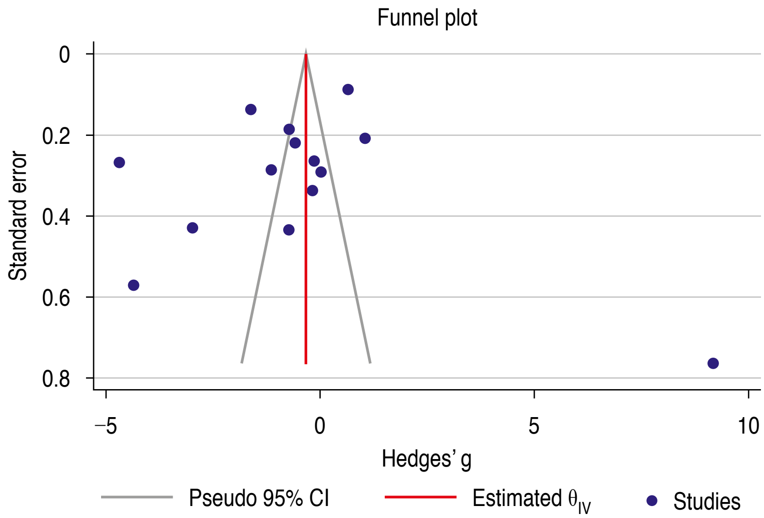


Figure 10: Funnel Plot. Statistical analysis of age variables.

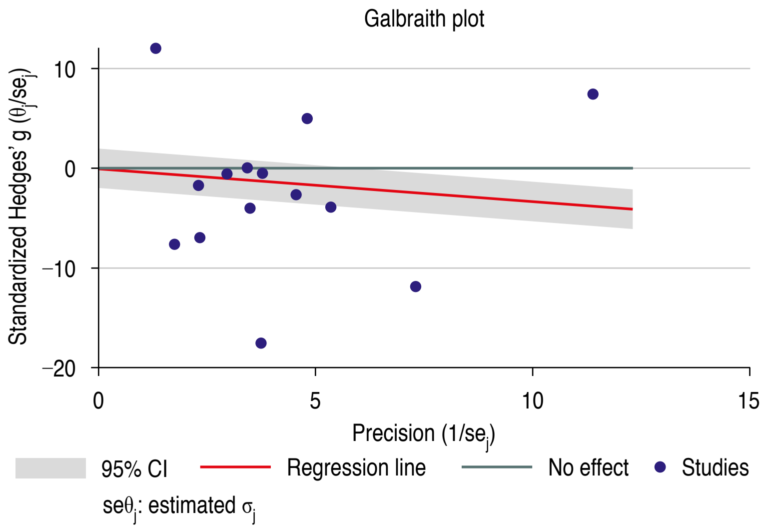


Figure 11: Galbraith Plot. Statistical analysis of age variables.

pathologies, specifically abnormal placentation and gynecological-pelvic tumors.

Concerning bleeding, the primary variable studied, our findings indicate that the application of prophylactic occlusion effectively reduced intraoperative bleeding. This result aligns with studies such as those by Zhao X,[28] Duan X,[20] Zeng C,[26] and Ye Y,[17] demonstrating that this method helps control and prevent intraoperative hemorrhage, thereby improving outcomes.

The most common complication observed was transient arterial thrombotic events, which were resolved with medical management. This was followed by emergency conversions to hysterectomy due to uncontrolled bleeding, predominantly in patients with abnormal placentation. However, this complication rate did not exceed 5% of the included population, suggesting that the risks associated with using this technique in elective surgery are acceptable.

Regarding the limitations of our research, we note the absence of randomized controlled trials specifically addressing the primary outcome of bleeding. Additionally, significant heterogeneity existed among the included studies, which we attempted to address through various stratification methods and statistical analyses.

In summary, our study suggests that the intravascular occlusion technique is effective in reducing intraoperative bleeding and may have significant clinical applications. Nevertheless, further research through controlled clinical trials is necessary to establish clear diagnostic inclusion criteria for participants and to individualize outcomes based on specific interventions within our population, thereby confirming these findings.

CONCLUSIONS

Intravascular balloon occlusion effectively reduces intraoperative blood loss in elective general non-cardiac surgical procedures with a high risk of hemorrhage. The most common complications include transient arterial thrombosis and localized issues at the puncture site.

While various clinical scenarios exist for applying this technique, the strongest evidence

Table 5: GRADE level of evidence and certainty. Intravascular balloon occlusion compared with not using intravascular occlusion balloon to reduce intraoperative bleeding.

Certainty assessment							N of patients		Effect			
N of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	intravascular occlusion balloon	not intravascular occlusion balloon	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Ioscovich A 2023	Non-randomised studies	Not serious	Not serious	Not serious	Not serious	Strong association	10 cases –	11 controls 0.0%	**OR −1.58** (−2.53 to −0.63)	– **0 fewer per 1,000** (from 0 fewer to 0 fewer)	⊕⊕⊕◯ Moderate	Important
Hao Z 2016	Non-randomised studies	Not serious	Not serious	Not serious	Not serious	Very strong association	18 cases –	23 controls 0.0%	**OR −3.98** (−5.03 to −2.93)	– **0 fewer per 1,000** (from 0 fewer to 0 fewer)	⊕⊕⊕⊕ High	Important
Zeng C 2017	Non-randomised studies	Not serious	Not serious	Not serious	Not serious	Very strong association	48 cases –	38 controls 0.0%	**OR −0.56** (−0.99 to −0.13)	– **0 fewer per 1,000** (from 0 fewer to 0 fewer)	⊕⊕⊕⊕ High	Important
Huo F 2021	Non-randomised studies	Not serious	Not serious	Not serious	Not serious	Very strong association	17/33 (51.5%)	16/33 (48.5%)	**OR 0.12** (−0.54 to 0.79)	**383 fewer per 1,000** (from 1,000 fewer to 58 fewer)	⊕⊕⊕⊕ High	Important
Papillon–Smith J 2020	Non-randomised studies	Not serious	Not serious	Not serious	Not serious	Strong association	47/79 (59.5%)	32/79 (40.5%)	**OR −0.76** (−1.22 to −0.30)	**1,000 fewer per 1,000** (from 1,000 fewer to 662 fewer)	⊕⊕⊕◯ Moderate	No important
Ye Y 2023	Non-randomised studies	Not serious	Not serious	Not serious	Not serious	Strong association	278/364 (76.4%)	86/364 (23.6%)	**OR −2.30** (−2.60 to −2.01)	**1,000 fewer per 1,000** (from 1,000 fewer to 1,000 fewer)	⊕⊕⊕◯ Moderate	Important

Continuos Table 5: GRADE level of evidence and certainty. Intravascular balloon occlusion compared with not using intravascular occlusion balloon to reduce intraoperative bleeding.

Certainty assessment							N of patients		Effect			
N of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	intravascular occlusion balloon	not intravascular occlusion balloon	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Wu Q 2016	Non-randomised studies	Not serious	Not serious	Not serious	Not serious	Very strong association	230/268 (85.8%)	38/268 (14.2%)	**OR −8.36** (−9.15 to −7.57)	**1,000 more per 1,000** (from 1,000 more to 1,000 more)	⊕⊕⊕⊕ High	Important
Peng W 2020	Non-randomised studies	Not serious	Not serious	Not serious	Not serious	Strong association	252/586 (43.0%)	296/586 (50.5%)	**OR 0.46** (0.29 to 0.63)	**186 fewer per 1,000** (from 277 fewer to 114 fewer)	⊕⊕⊕◯ Moderate	Important
Zhao X 2016	Non-randomised studies	Not serious	Not serious	Not serious	Not serious	Strong association	23 cases –	34 controls 0.0%	**OR −18.28** (−21.68 to −14.89)	– **0 fewer per 1,000** (from 0 fewer to 0 fewer)	⊕⊕⊕◯ Moderate	No important
Duan X 2018	Non-randomised studies	Not serious	Not serious	Not serious	Not serious	Strong association	22/45 (48.9%)	23/45 (51.1%)	**OR −4.26** (−5.31 to −3.21)	**778 more per 1,000** (from 709 more to 913 more)	⊕⊕⊕◯ Moderate	Important
Wang Y 2020	Non-randomised studies	Not serious	Not serious	Not serious	Serious	Strong association	600/623 (96.3%)	23/623 (3.7%)	**OR −3.62** (−4.08 to −3.16)	**198 fewer per 1,000** (from 222 fewer to 175 fewer)	⊕⊕◯◯ Low	No important
Peng Y 2020	Non-randomised studies	Not serious	Not serious	Not serious	Not serious	Strong association	48/104 (46.2%)	56/104 (53.8%)	**OR 0.37** (−0.02 to 0.76)	**237 fewer per 1,000** (from 562 fewer to 68 fewer)	⊕⊕⊕◯ Moderate	Important

focuses on obstetric procedures, particularly those involving abnormal placentation.

Further research is essential, especially controlled clinical studies that establish clear diagnostic inclusion criteria for participants. Additionally, individualizing results based on specific interventions within our population is crucial to validate these findings.

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