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REVIEW ARTICLE

ADM-assisted prepectoral breast reconstruction is not associated with high complication rate as before: a Meta-analysis

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ABSTRACT

Implant-related breast reconstruction can be divided into subpectoral breast reconstruction (SPBR) and prepectoral breast reconstruction (PPBR) according to the different anatomical planes. The previous stereotype was that PPBR had a high complication rate and was not suitable for clinical use. However, with the emergence of acellular dermal matrix (ADM), the clinical effect of PPBR has been improved. To compare the outcomes difference between SPBR and PPBR, We conducted this meta-analysis. Articles on SPBR versus PPBR were searched in PubMed, Web of Sciences, Embase, and Cochrane databases, strictly following the PRISMA guidelines. According to the set criteria, we included the literature that met the requirements. Extracted data were the incidence of adverse events and the duration of drainage. Results show that SPBR has a higher incidence rate in capsular contracture, animation deformity, infection, hematoma and delayed healing wound than PPBR. There are no significant differences in skin flap necrosis, seroma, implant loss, reoperation and duration of drainage between the two groups. Hence, PPBR is no longer a high complication surgical method and can be used in the clinical practice. However, there are few large sample studies at present, so it is necessary to carry out further studies on PPBR.

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KEYWORDS
Prepectoral; submuscular; breast reconstruction; implant

Introduction

In February 2021, the World Health Organisation (WHO) published a report stating that breast cancer has now surpassed lung cancer and become the most common tumour worldwide [1]. With social progress and the development of science, breast cancer has become one of the tumours with an excellent prognosis, leading to the continuously improving survival rate of patients [2]. At the same time, in order to make patients better integrate into society, breast reconstruction has attracted the attention of scholars and patients [3]. Implant-related breast reconstruction is the most common type now, usually placing the prosthesis behind the pectoralis major muscle, called subpectoral breast reconstruction (SPBR) [4]. However, a novel revision of an ancient surgical procedure—prepectoral breast reconstruction (PPBR)—is now gaining popularity among clinicians [5].

Unlike PPBR that people used earlier, acellular dermal matrix (ADM) is now commonly used for PPBR to reduce complications [6]. ADM is a biosynthetic substance of human, bovine, or pig origin, in which the immune antigens are processed during the manufacturing process, but the scaffold structure is retained [4]. As a result, ADM promotes angiogenesis and tissue growth. ADM was first applied to burn patients in 1995 and has since been gradually popularised by surgeons [5]. In 2001, ADM was used for the first time in breast reconstruction, opening its doors to of breast reconstruction [6]. Over the next 20 years, ADM has been widely used in various forms of breast reconstruction.

PPBR has achieved good clinical results, but it also raises a question for clinicians: which one is better and safer, SPBR or PPBR? To address this issue and provide evidence for surgical choice, we conducted a detailed meta-analysis and compared the differences in outcomes between SPBR and PPBR.

Methods

Search strategy

Two researchers worked together to search and screen literature in PubMed, Web of Science, and the Cochrane Library. The search terms included breast reconstruction or mammaplasty, prepectoral or subcutaneous, subpectoral or submuscular, implant or tissue expander, and ADM or acellular dermal matrix. The time limit was 1 January 1970 to 21 March 2021. In case of a dispute, two researchers discussed the issue strictly. If there was still a disagreement, we found a third party to solve the problem.

Inclusion and exclusion criteria

We developed detailed inclusion and exclusion criteria. The subjects in the literature were patients with mastectomy or prophylactic mastectomy for breast cancer. The study design was a randomised clinical trial, cohort study or retrospective analysis with detailed clinical data.

We excluded articles that did not meet the requirements of the study design, articles with missing data, articles that were

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Table 1. Inclusion criteria and exclusion criteria.

Inclusion criteria:
1. Clinical subjects included in the literature were patients undergoing breast reconstruction due to breast tumors or prophylactic mastectomy;
2. Randomized controlled trial, cohort study and retrospective analysis were included in the studies;
3. Literature including relevant outcomes of SPBR and PPBR can provide detailed original data.
Exclusion criteria:
1. The research design does not conform to the above methods, or the design is not rigorous;
2. Lacking of relevant data;
(3) Duplicate publications;
(4) Reviews, meta-analysis and other articles without clinical research data;

republished and articles of inappropriate literature type. The selection criteria are summarised in Table 1.

Data extraction

Two researchers screened the literature strictly according to the above inclusion and exclusion criteria and extracted relevant information, including the following: (1) The basic characteristics of the literature: name of author, publication time, number of SPBR and PPBR subjects, age, BMI, history of diabetes, smoking history and surgical materials. (2) Outcome indicators: incidence of common adverse events, duration of drainage, and reoperation rate.

Statistical analysis

The software RevMan 5.4.1 was used for data entry and analysis. Firstly, the heterogeneity of the data was examined. If $I^2 \leq 50\%$, the heterogeneity was considered not obvious, and the fixed effect model was used to merge and analyse the data. If $I^2 > 50\%$, statistical heterogeneity was considered, and the random effect model was used for data consolidation and analysis. If the data were continuous variables, mean difference (MD) was used as the statistical effect indicator; if the data were dichotomous variables, odds ratio (OR) was used as the statistical effect indicator. 0.05 was selected as the significant level, and when $p < .05$, the difference between the two groups was statistically significant. Publication bias was judged according to funnel plots. According to the Cochran manual, the asymmetry test (i.e. funnel plots) had better guiding significance when the number of included studies exceeded or was equal to 10. Therefore, publication bias evaluation was not performed if less than 10 studies were included in the analysis [7].

Results

Search result

We retrieved 276 articles in the database and added 130 articles by reading the references. After eliminating duplicates, 297 pieces of literature were found. First, 108 references were excluded by reading titles and abstracts. Then, after reading the entire text in detail, 143 references that did not meet the inclusion criteria were excluded. Then the literature with incomplete data was excluded, and finally, 28 pieces of literature were included [8–35]. The flow chart is as follows (Figure 1).

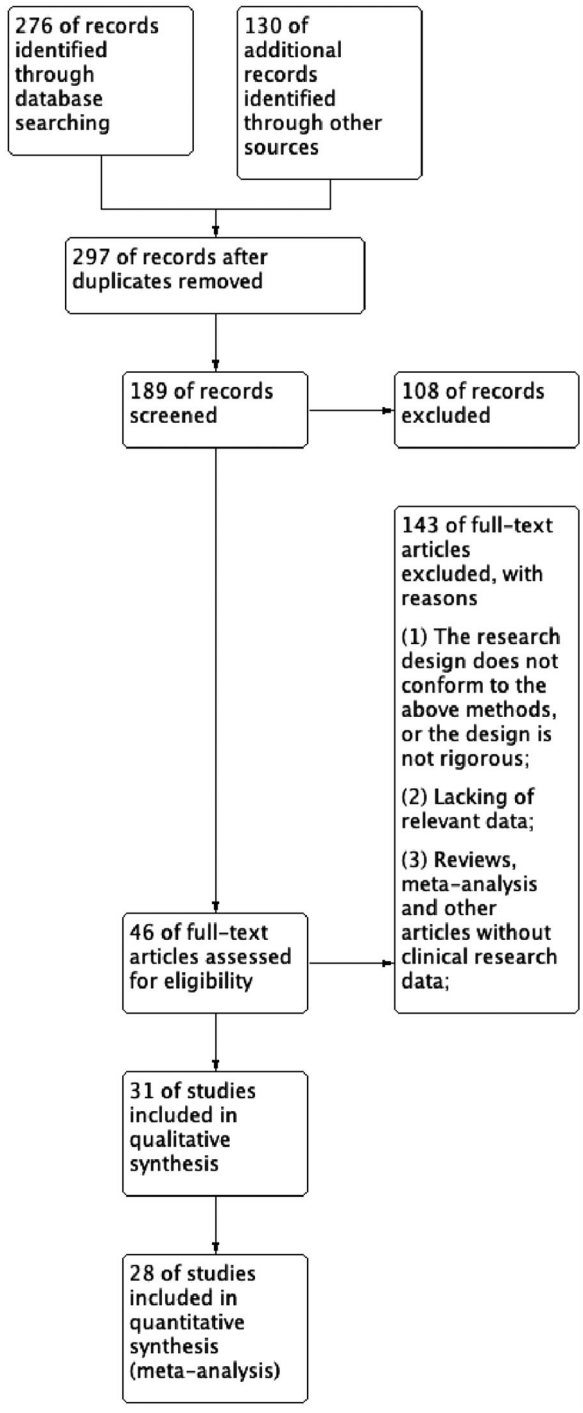


Figure 1. Flow diagram.

Study design

A total of 4297 patients were included in the 28 studies, including 2277 patients (2.591 breasts) undergoing SPBR and 2020 patients (2784 breasts) undergoing PPBR. In addition, among the 28 included literature, there were 26 retrospective reviews and two prospective cohort studies (Table 2).

Characteristics of articles

Among the articles we selected, the publication time ranged from 2018 to 2020. Two of the studies were prospective cohort studies and the rest were retrospective analyses. The total study span ranged from 2009 to 2019. Given the presence of bilateral breast

reconstruction in some studies, we put the number of breasts in parentheses after the number of patients. Significantly that the complication rates are all based on the number of breasts, not the number of patients. Two of the articles used ADM combined with Vicryl . And the rest applied ADM only. The ADM and Vicryl used in these articles were in the form of mesh. Eleven articles used direct implantation (one-stage breast reconstruction), 12 articles used two-stage breast reconstruction related to the expander, and five articles used both methods (Table 3).

Characteristics of patients

We extracted the data of patients' age, BMI, smoking history, and diabetes history in the included literature and did the difference analysis (Table 4).

Capsular contracture

Eleven studies reported the incidence of capsular contracture between SPBR and PPBR (Figure 2(A)). Two of the articles used ADM combined with Vicryl. And the rest applied ADM only. The rate of capsular contracture in the subpectoral group was 8.2% (110 of 1336), compared to the 5.8% (68 of 1178) within the prepectoral cohort. There was no remarkable heterogeneity across studies (I^2 = 39%, p = .09), with fixed-effects modelling demonstrating significantly higher odds of capsular contracture in the subpectoral group compared to prepectoral group (OR = 1.46, 95% CI: 1.04–2.04, p = .03). No publication bias could be observed *via* the funnel plot (Figure 2(B)).

Table 2. Study design.

Research design	No. studies
Prospective cohort	2
Randomized clinical trial	0
Retrospective review	26
Operation timing	No. studies
One stage	11
Two stage	12
Both	5
Type of Mesh	No. studies
ADM	26
Tiloop	0
Vicryl + ADM	2

Animation deformity

Five articles reported the incidence of animation deformity (Figure 3), which was 55.2% in the SPBR group and 0% in the PPBR group (Figure 3). The heterogeneity among groups was significant (I^2 = 64%, p = .02), with random-effects modelling demonstrating that the incidence of animation deformity in SPBR was significantly higher than that in PPBR (OR = 30.60, 95% CI: 3.41 − 274.29, p = .002).

Skin flap necrosis

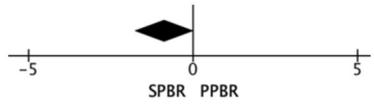
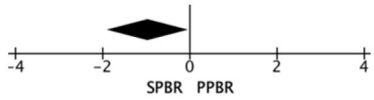
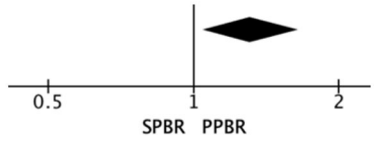
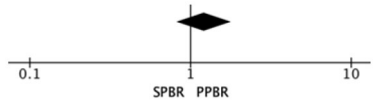
Twenty-three articles reported the incidence of skin flap necrosis in the two groups: 7.4% (176 of 2388) in the SPBR group and 6.4% (168 of 2615) in the PPBR group (Figure 4(A)). One of the articles used ADM combined with Vicryl. And the rest applied ADM only. The heterogeneity between each group was not significant (I^2 = 24%, p = .14), with fixed-effects modelling demonstrating that there was no significant difference in skin flap necrosis between SPBR and PPBR groups (OR = 1.16, 95% CI: 0.92–1.47, p = .21), and the funnel plot did not show publication bias (Figure 4(B)).

Table 3. Characteristics of articles.

Study ID	Research design*	Study duration	SPBR patients (Breasts), *n*	PPBR patients (Breasts), *n*	Surgical material	Operation timing	Level of evidence
Alex, 2019	R	2015–2017	38 (56)	39 (60)	ADM	2-stage	III
Arash, 2019	R	2017–2018	40 (69)	40 (69)	ADM	2-stage	III
Azalia, 2020	R	2014–2018	202 (202)	203 (203)	ADM	1-stage and 2-stage	III
Benjamin, 2017	P	2016	12 (19)	28 (43)	ADM	1-stage	III
Blair, 2018	R	2016–2017	69 (124)	32 (60)	ADM	2-stage	III
Catherin, 2018	R	2010–2017	100 (163)	274 (426)	ADM	1-stage and 2-stage	III
Diego, 2020	R	2010–2018	470 (509)	172 (207)	ADM	1-stage	III
Ewa, 2018	R	2011–2017	30 (45)	24 (42)	ADM	2-stage	III
Fabinshy, 2019	R	2011–2013	29 (29)	34 (34)	ADM	1-stage	II
Franca, 2020	R	2016–2018	117 (184)	169 (308)	ADM	2-stage	III
Glenda, 2020	R	2013–2017	55 (55)	39 (39)	ADM	1-stage	III
Gurjot, 2018	R	2011–2016	109 (109)	26 (26)	ADM	2-stage	III
Jeong-Hoon, 2020	R	2015–2020	114 (114)	53 (53)	ADM	1-stage	III
Joon, 2021	R	2018–2019	14 (14)	20 (20)	ADM	1-stage	III
Joseph, 2019	R	2012–2016	83 (147)	110 (189)	ADM	2-stage	III
Jun, 2019	R	2017–2018	32 (32)	47 (47)	ADM	1-stage and 2-stage	III
Kassandra, 2019	R	2014–2018	142 (238)	114 (183)	Vicryl + ADM	1-stage	III
Libby, 2018	R	2015–2017	58 (98)	94 (160)	ADM	1-stage and 2-stage	III
Maurice, 2017	R	2015–2017	50 (83)	39 (62)	ADM	1-stage and 2-stage	III
Mihir, 2018	R	2015–2017	69 (83)	61 (71)	ADM	1-stage	III
Mustafa, 2019	R	2009–2016	22 (36)	33 (50)	ADM	2-stage	III
Nicholas, 2020	R	2014–2018	103 (202)	92 (174)	ADM	2-stage	III
Nikhil, 2020	R	2015–2018	27 (49)	20 (32)	Vicryl + ADM	1-stage	III
Oscar, 2020	R	2011–2018	69 (124)	100 (187)	ADM	1-stage	III
Oscar, 2019	R	2012–2016	42 (69)	33 (55)	ADM	2-stage	III
Patel AA, 2019	R	2009–2018	54 (73)	35 (52)	ADM	2-stage	III
Shayda, 2020	P	2016–2017	67 (112)	62 (112)	ADM	1-stage	III
Young, 2021	R	2017–2019	60 (62)	27 (27)	ADM	2-stage	III

*R: Retrospective; P: Prospective.

Table 4. Characteristics of patients.

Patient information	Variable types	No. Studies	Heterogeneity	Effect of the model	*P*	Forest plot
Age	Continuous	19	58%	Random	.06	
BMI	Continuous	19	96%	Random	.05	
Smoking	Dichotomous	20	2%	Fixed	.02	
Diabetes	Dichotomous	14	0%	Fixed	.34	

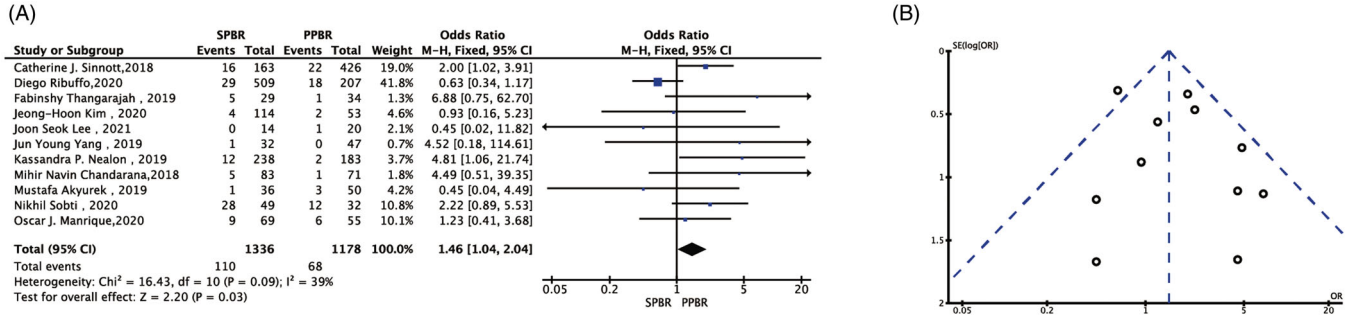


Figure 2. (A) SPBR vs. PPBR in capsular contracture. (B) Funnel plot.

Infection

Twenty-three studies compared the incidence of infection between the two groups, with SPBR of 6.5% (173 of 2642) and PPBR of 5.5% (145 of 2621) (Figure 5(A)). Two of the articles used ADM combined with Vicryl. And the rest applied ADM only. There was no significant heterogeneity among the studies (I^2 = 12%, p = .30), with fixed-effects modelling demonstrating that the incidence of infection was slightly higher in SPBR than in PPBR (OR = 1.29, 95% CI: 1.02–1.63, p = .04). The funnel plot did not show remarkable publication bias (Figure 5(B)).

Seroma

The incidence of seroma in the two groups was reported in 21 articles. SPBR was 7.0% (197 of 2821) and PPBR was 7.2% (198 of 2763) (Figure 6(A)). One of the articles used ADM combined with Vicryl. And the rest applied ADM only. There was no significant heterogeneity among the studies (I^2 = 29%, p = .10), with fixed-effects modelling demonstrating that there was no significant difference in the occurrence of seroma between SPBR and PPBR (OR = 0.89, 95% CI: 0.71–1.11, p = .29). The funnel plot did not show remarkable publication bias (Figure 6(B)).

Hematoma

Nineteen studies reported the incidence of hematoma in the two groups, with SPBR of 3.2% (86 of 2709) and PPBR of 1.86% (49 of 2604). Two of the articles used ADM combined with Vicryl. And the rest applied ADM only. There was no significant heterogeneity among the studies (I^2 = 1%, p = .44), with fixed-effects modelling demonstrating that SPBR had a higher incidence of hematoma (OR = 1.46, 95% CI: 1.02–2.09, p = .04; Figure 7(A)). The funnel plot did not show remarkable publication bias (Figure 7(B)).

Implant loss

Implant loss was reported in 14 papers, 4.5% in SPBR (90 of 1981) and 3.8% in PPBR (72 of 1883) (Figure 8(A)). One of the articles used ADM combined with Vicryl. And the rest applied ADM only. There was no significant heterogeneity among the studies (I^2 = 0%, p = .94), with fixed-effects modelling demonstrating that there was no significant difference in the incidence of implant loss between SPBR and PPBR (OR = 1.27, 95% CI: 0.91–1.76, p = .16). The funnel plot did not show remarkable publication bias (Figure 8(B)).

Reoperation

Seven studies reported the incidence of reoperation, 6.8% in SPBR (58 of 854) and 7.8% in PPBR (53 of 680). One of the articles used ADM combined with Vicryl. And the rest applied ADM only. There was no significant heterogeneity among the groups (I^2 = 20%, p = .27; Figure 9), with random-effects modelling demonstrating that there was no significant difference in the incidence of implant loss between the two groups (OR = 0.85, 95% CI: 0.57–1.27, p = .43; Figure 9).

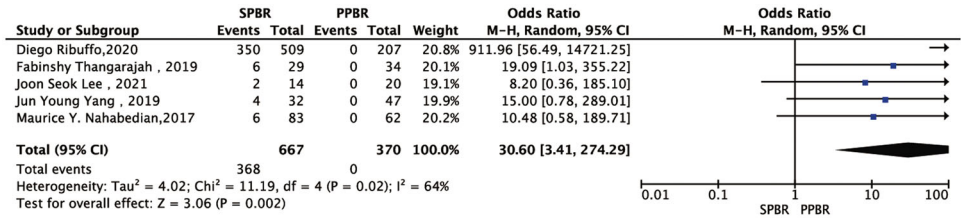


Figure 3. SPBR vs. PPBR in animation deformity.

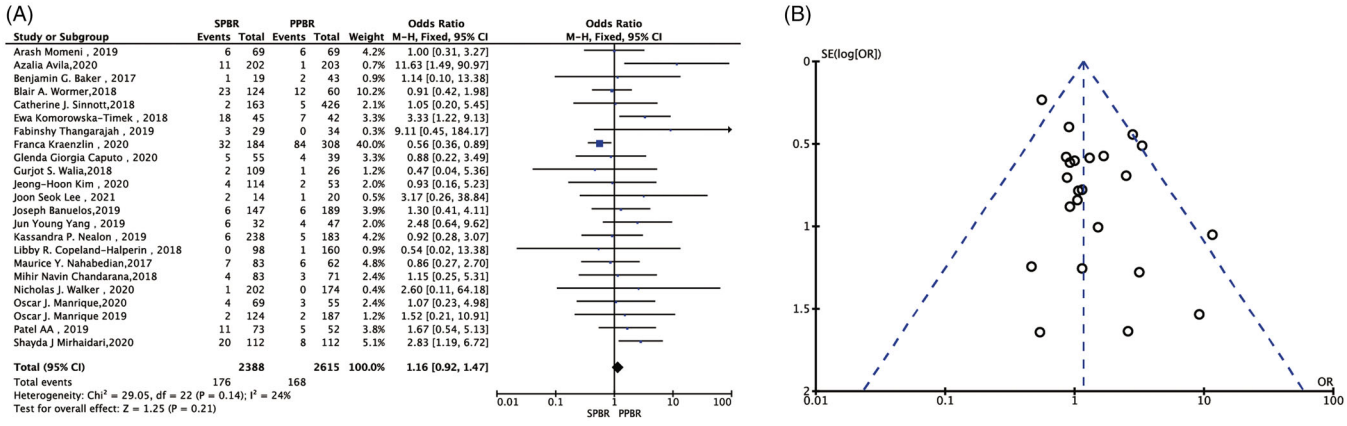


Figure 4. (A) SPBR vs. PPBR in skin flap necrosis. (B) Funnel plot.

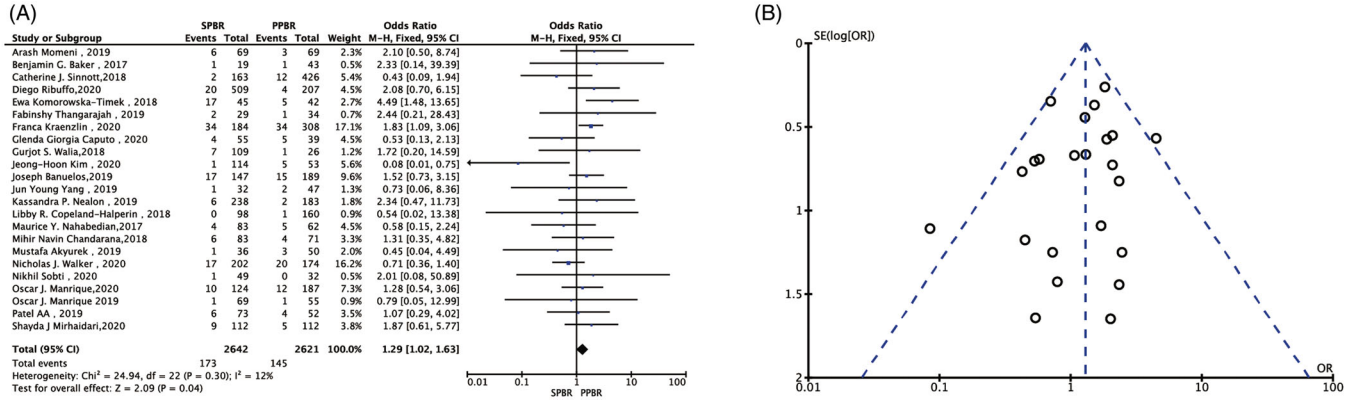


Figure 5. (A) SPBR vs. PPBR in infection. (B) Funnel plot.

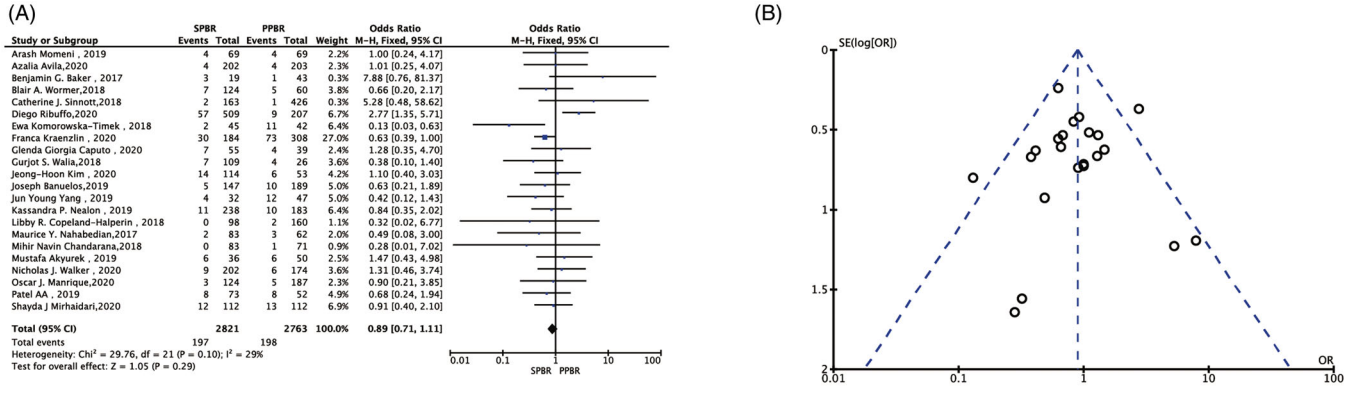


Figure 6. (A) SPBR vs. PPBR in seroma. (B) Funnel plot.

Delayed healing wound

There are three studies on the occurrence of delayed healing wounds in two groups, 8.3% (22 of 265) in SPBR and 5.0% (13 of 260) in PPBR (Figure 10). These three articles used ADM only. There was no significant heterogeneity among the studies (I^2 = 0%, p = .40), with fixed-effects modelling

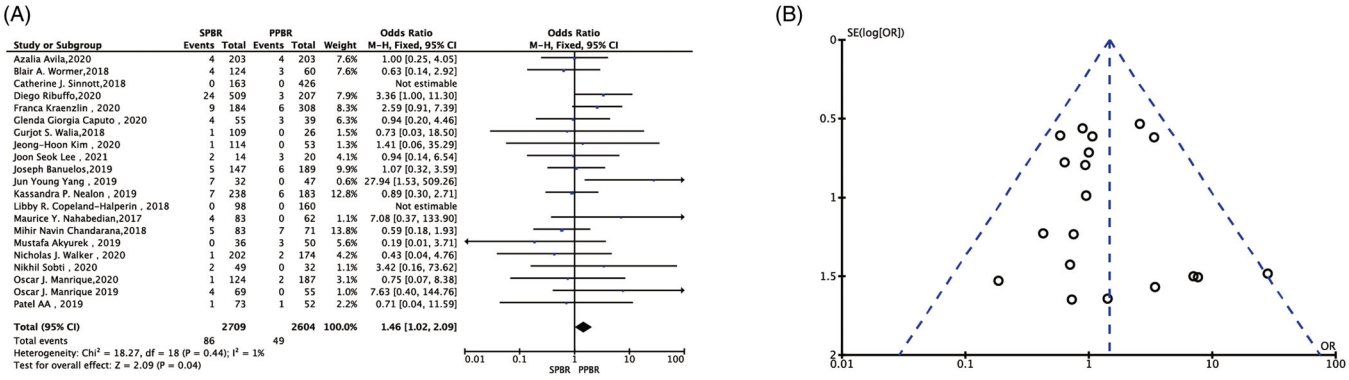


Figure 7. (A) SPBR vs. PPBR in a hematoma. (B) Funnel plot.

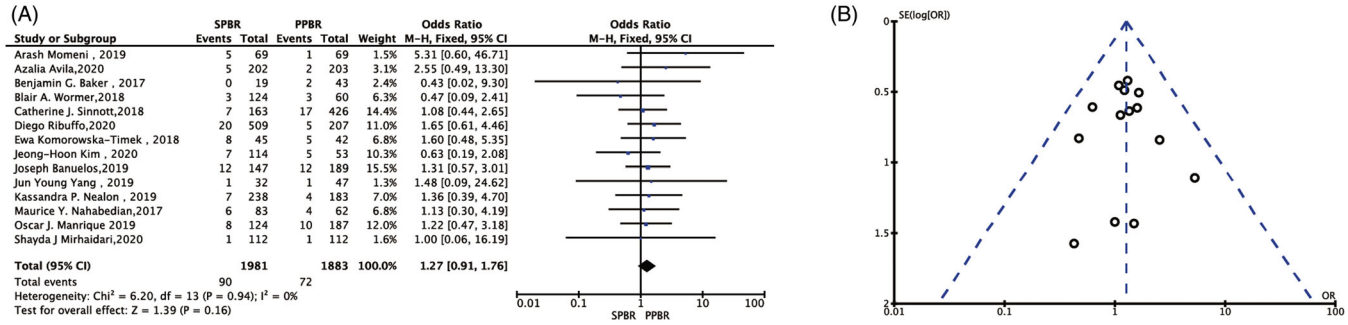


Figure 8. (A) SPBR vs. PPBR in implant loss. (B) Funnel plot.

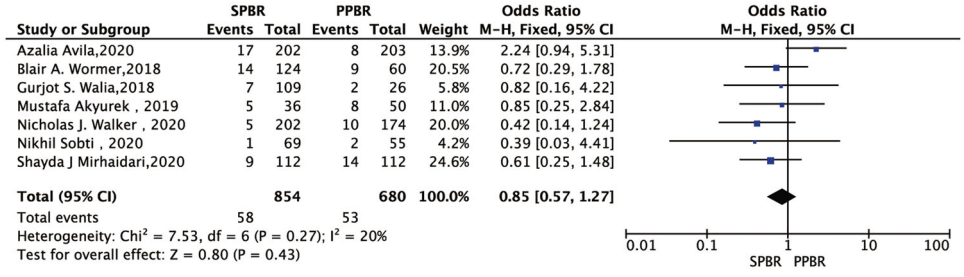


Figure 9. SPBR vs. PPBR in reoperation.

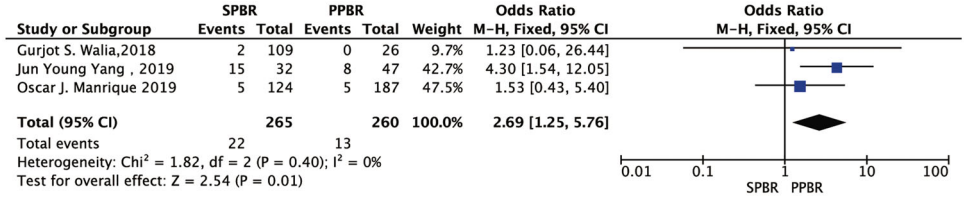


Figure 10. SPBR vs. PPBR in delayed healing wound.

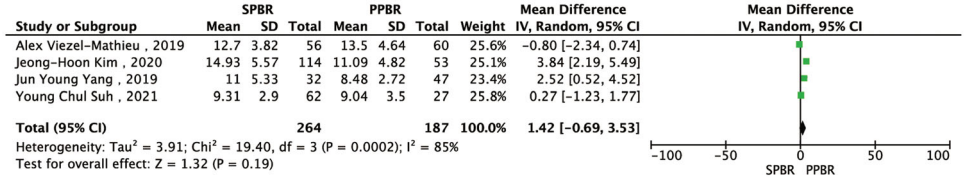


Figure 11. SPBR vs. PPBR in duration of drainage.

demonstrating that SPBR has a higher incidence of delayed healing wound than PPBR (OR = 2.69, 95% CI: 1.25–5.76, $p = .01$; Figure 10).

Duration of drainage

The drainage time was involved in four studies. These four articles used ADM only. There was obvious heterogeneity among each group ($I^2 = 85\%$, $p = .0002$), with random-effects modelling

demonstrating no significant difference in the duration of drainage between the two groups (MD = 1.42, 95% CI: −0.69–3.53, $p = .19$; Figure 11).

Discussion

Implant-related breast reconstruction is now a mature surgical procedure, and the direction of its development is also changing to improve satisfaction and reduce postoperative complications [36]. In the 1970s, surgeons placed implants in front of the chest muscle, but the high incidence of postoperative complications, such as infection, capsular contracture, and visibility of the prosthesis, led to the procedure's abandonment [37]. For a long time since then, doctors have placed implants behind the pectoralis major muscle to increase soft-tissue thickness and reduce complications [38]. However, with the development of materials science and the birth of ADM, the complications of PPBR in the past can be avoided, causing that PPBR gets the popularity of surgeons [39]. Headon et al. found that the use of ADM could reduce the capsular contracture rate of PPBR through a single-centred clinical trial, and Liu et al. reached the same conclusion through meta-analysis [40,41]. ADM was proved to reduce the local inflammatory response and inhibit capsule formation [42]. In addition, the ADM stitched to the inframammary fold of the breast can mediate a better fit between the implant and the inframammary fold, thus reducing the occurrence of 'window shading,' making the shape more beautiful [43]. ADM is widely used in PPBR because of its advantages. Onesti et al. conducted a single-centred clinical study and found that the use of ADM could reduce the incidence of seroma and capsular contracture in PPBR [6]. At the same time, it improves subjective indicators such as postoperative breast satisfaction and sexual satisfaction, which proves the advantages of ADM in PPBR application [6].

At present, it seems that a good grasp of the indications of SPBR and PPBR and a proper choice of specific patients can achieve satisfactory results for both. However, to study the differences in outcomes between the two groups and better understand the indications, it is necessary to conduct a meta-analysis of the studies related to the two groups. Therefore, we included 28 articles for a meta-analysis, and the results showed that compared with PPBR, SPBR had a higher rate of capsular contracture, animation deformity, infection, hematoma, and delayed healing.

Capsular contracture is a fibrotic response to an implant in the normal human body [44]. In moderation, it can maintain the implant in its normal position, but in excess, it can lead to breast pain and deformity [45]. The pathogenesis of capsular contracture includes chronic irritation of the prosthesis surface, local inflammation, immune infiltration, and radiotherapy injury [46]. Previously, many scholars proposed that the capsular contracture rate of SPBR was lower than that of PPBR [28], but recent clinical studies and new meta-analyses have shown that the capsular contracture rate of SPBR is higher than that of PPBR or the difference is low. Our meta-analysis shows a higher rate of capsular contracture in SPBR, which may be speculated to be related to the large amount of tissue excised during SPBR operation, strong inflammatory response, and postoperative dysfunction [47]. However, due to the lack of reports on the radiotherapy history of patients with capsular contracture in the literature, further studies are needed to confirm this.

Animation deformity is a complication seriously affecting the beauty of the breast and the degree of satisfaction, especially for those patients with a demanding chest muscle movement function [48]. It is caused by the chest muscle contraction, which induces the unnatural movement of the prosthesis behind the muscle, leading to the shape deformity of the breast [49]. Our meta-analysis shows that the animation deformity rate of SPBR is high, while no animation deformity can be observed in the PPBR group. Therefore, PPBR can serve as a method to treat patients with animation deformity [50].

With the increasing number of skin-sparing mastectomies (SSM) and nipple-sparing mastectomies (NSM), breast aesthetics has steadily improved, but the ensuing flap necrosis has also puzzled many doctors and patients [51]. The skin blood supply of the breast mainly comes from the branches of the lateral thoracic artery, internal thoracic artery and intercostal artery, and the intraoperative injury of these arteries may lead to the occurrence of skin flap necrosis [52]. The necrosis rate of SPBR and PPBR flaps has always been controversial. Azalia Avila found that SPBR has had a higher probability of skin flap necrosis and speculated that more isolated tissues might be the reason [10]. While Franca Kraenzlin found that PPBR had a higher probability of skin flap necrosis and speculated that it might be because the prosthesis is placed directly under the skin, which increases the flap tension, leading to an increased probability of skin flap necrosis [17]. There was no significant difference in the probability of skin flap necrosis between the two groups in our analysis. However, it should be emphasised that flap necrosis is associated with many factors, including smoking, diabetes, and immune diseases, which may impact the comparison between the two groups [53]. It is worth mentioning that at present, many scholars point out that PPBR puts the prosthesis in the subcutaneous plane, so the requirements for the skin flap are strict. Therefore, smoking, diabetes, and local radiotherapy history can be regarded as contraindications of PPBR [54]. Moreover, flap thickness of more than 1 cm is considered to be a surgical condition for PPBR [23].

Infection is one of the most common complications after breast reconstruction, often leading to the increased hospital stay, increased costs, physical pain, and even the removal of prostheses [55]. A detailed and comprehensive preoperative assessment of the patient's basic condition, the use of prophylactic antibiotics, and strict intraoperative aseptic procedures can reduce the rate of postoperative infection [56]. In our analysis, the infection rate of SPBR was higher. It may be related to more excision injuries during the operation, which may also explain why the analysis results show a higher rate of hematoma formation in SPBR.

Similarly, we found a higher rate of delayed wound healing in SPBR than in PPBR. Therefore, the previous conclusion explains that SPBR has more intraoperative injury and bleeding, which increases the possibility of infection and the probability of delayed wound healing [57]. However, only three studies compared the delayed healing rate between the two groups, with a small number of samples, so the results were not rigorous. Therefore, more studies are needed to confirm this conclusion.

It can also be seen that SPBR and PPBR have no significant differences in the incidence of seroma, implant loss, and reoperation, which can explain the safety of PPBR to some extent. Furthermore, there was no significant difference in the drainage time between the two groups, indicating that different surgical methods would not cause significant changes in the postoperative drainage time.

In conclusion, PPBR has good safety, and the complication rate is not as high as before. But there are limitations to this study. This study did not include any RCTs, lowering the level of evidence. In addition, there are differences in the design methods of various studies. Moreover, some studies have limited the study population, such as obese patients. Nevertheless, the results of

this study can also reveal a truth that has been recognised by many authoritative scholars: PPBR is no longer a surgical procedure with high complications.

Conclusion

The stereotype of prepectoral breast reconstruction was that it had high complications and was prone to failure in the past. However, with the advent of ADM, PPBR's complications have decreased, leading to renewed interest in it. To explore the safety of current PPBR, we conducted this meta-analysis, and the results were encouraging: PPBR had a lower rate of capsular contracture, infection, hematoma and delayed healing wound, with the incidence of other common complications not significantly different from SPBR. This indicates that PPBR is now a safe surgical method, and its complications are no longer as terrible as before. Therefore, it can be applied in clinical practice under the condition of the strict selection of indications. While there are still few studies on PPBR, we expect more clinical trials to prove its safety.

Author contributions

Jiaheng Xie, Yuan Cao, Shujie Ruan, Mengmeng Ou, Pan Yu: acquisition of data, analyzing and interpretation of data, drafting the article; Jingping Shi, Zhechen Zhu, Ming Wang,: designing, revising, and guiding the study. The authors read and approved the final manuscript.

Disclosure statement

The authors declare that they have no competing interests.

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Data availability statement

All the data for this article can be found on Pubmed.

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