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Original Article

Acellular bovine pericardium matrix in immediate breast reconstruction compared with conventional implant-based breast reconstruction

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ABSTRACT

Background: Acellular Bovine Pericardium Matrix (ABPM) is a new material in implant-based breast reconstruction (IBBR). Few studies have reported on its outcome and complications worldwide and most studies were without a control group. Our aim was to compare its use in IBBR with the other two conventional implant-based reconstruction methods.

Methods: A retrospective review of patients undergoing IBBR from January to December 2018 was performed. Patients were assigned to the ABPM-assisted IBBR (group A), latissimus dorsi-assisted IBBR (group B) and two-stage IBBR (group C). Patients' post-operative

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complications, cost-effectiveness and Quality of Life were compared.

Results: 100 patients with 100 breasts were included in the study. No complications occurred in group C ($n = 11$). No significant differences were noted between group A ($n = 44$) and group B ($n = 45$) in terms of overall complications (9.1% vs 11.1%, $p = 0.973$). Group B had the longest operative duration (310.8 ± 62.3 min, $p<0.001$). The cost of hospitalization forthe three groups was $8051.3 ± 849.2, $7566.0 ± 1172.7 and $7896.5 ± 1762.2, respectively ($p = 0.128$). The postoperative Breast-Q scores were similar across the three groups.

Conclusions: ABPM demonstrated acceptable complication rates, cost-effectiveness and quality of life outcomes when compared to LD-assisted IBBR and two-stage IBBR.

Introduction

Implant-based breast reconstruction (IBBR) is the main surgical technique used for breast reconstruction worldwide.[1] In 1981 Gruber et al. first presented submuscular implant reconstruction.[2] When the subpectoral pocket is not adequate for immediate implant placement, two-stage IBBR using tissue expansion (TE) in the first stage can be used.[3] But this requires two procedures, and multiple expansion visits to the outpatient clinic. This also increases the economic burden.[4]

In 2005 Breuing first used acellular dermal matrix (ADM) in IBBR.[5] In recent years many published reports have described experiences with various ADM products in immediate IBBR.[6–8] From a cosmetic outcome viewpoint, many authors consider ADM-assisted IBBR a valuable reconstruction method.[4,7] However, the complication rates and costs in immediate ADM-assisted IBBR tend to be higher when compared to two-stage IBBR.[9,10]

The use of acellular bovine pericardium matrix (ABPM), in IBBR was by described in 2011 by Borgognone et al.[11] It is similar to ADMs in structure, but has more readily available source material and is less expensive.[12,13] At present, there is little published data on ABPM and most are single-arm studies.[14,15] To date the largest published series of ABPM was a cohort of 54 patients.[16] There has been only one publication that compared ADM to ABPM in IBBR.[15] But there have been no reports comparing this material with other IBBR methods. This retrospective study aimed to investigate the advantages and disadvantages of one-staged ABPM-assisted IBBR compared to latissimus dorsi (LD) flap assisted reconstruction and two stage IBBR in terms of complications, cost-effectiveness and quality of life (QoL).

Patients and methods

A retrospective review was performed on all patients who underwent IBBR after nipple-sparing mastectomy (NSM), skin-sparing mastectomy (SSM) or modified radical mastectomy in our department between January 2018 and December 2018. We divided the patients into 3 groups :the ABPM group (Group A); LD assisted group (Group B); and TE group without ABPM(Group C). Demographic data (e.g., age, body mass index), medical history (e.g., diabetes, hypertension, smoking, chemotherapy and radiation therapy) and surgical data (e.g., methods, size of implant, complications, duration of surgery and cost of hospitalization) were collected for each patient. Complications were listed as minor or major. Minor complications were defined as those events that could be treated conservatively.

Major complications were defined as those events that required additional surgical intervention. The IBBR with subpectoral implant placement was carried out by suturing the ABPM or LD to the inframammary fold inferiorly, lower edge of the pectoralis muscle superiorly and the serratus anterior muscle laterally to complete inferior pole coverage of the implant. We used an ABPM extracted from solvent preserved bovine pericardium (I-realTM breast patch by GUANHAO BIOTECH – China), which was the first product approved for breast reconstruction in China. It is a thin fenestrated product composed of non-crosslinked acellular collagen matrix of bovine pericardial origin measuring100×120mm. Intravenous perioperative antibiotics were used for all patients (Cefazolin 2 g or clindamycin 0.6 g was given 30 min before surgery and repeated if the surgery lasted more than 3 h). Before insertion, ABPM was washed 3 times in 0.9% normal saline and then soaked in dexamethasone and antibiotic solution for 10 min. The drains were removed when output was less than 30 mL in 24 h.

We compared the cost-effectiveness of different procedures in terms of the duration of surgery and the cost of hospitalization. The duration of the operation was the total time taken for the skin-sparing mastectomy and the breast reconstruction (including the time required for the second operation to replace TE with a definitive implant). Direct costs were calculated by total cost during hospitalization, including all materials, surgery, anesthesia, and other hospitalization costs. Costs were estimated in US dollars based on cost statements from Tianjin Medical University Cancer Institute and Hospital (Tianjin, China). Patients were invited to complete a single postoperative BREAST-Q questionnaire during follow-up. BREAST-Q outcome measures (satisfaction with breasts, satisfaction with outcome, psychosocial well-being, sexual well-being, physical well-being, satisfaction with information, satisfaction with surgeon and satisfaction with medical staff from) were calculated using the Q-Score Scoring Software package.

Analysis of variance (ANOVA) and Chi-square was used to analyze differences in patients' characteristics and postoperative outcomes between the different surgical groups. $p<0.05$ was considered statistically significant. Statistical analysis was performed using the IBM SSPS Statistics 22.0; SPSS Inc. software package.

Results

Demographics

A total of 100 patients (100 breasts) underwent implant-based breast reconstructions (IBBR) by four surgeons at our department between January and December 2018. Forty-four patients (Group A) underwent ABPM-assisted IBBR (44%), 45 patients (Group B) underwent unilateral LD-assisted IBBR (45%), and 11 patients (Group C) underwent two-stage IBBR (11%).

There were no statistically significant differences between the groups in terms of patient demographics (i.e., age, median body mass index) or medical history (i.e., diabetes, hypertension, smoking, chemotherapy, and radiation therapy). Patient characteristics are shown in Table 1. More than half the patients received neoadjuvant chemotherapy, and 9% received radiation treatment postoperatively. The median age for Group A was 38 years, Group B 40.8 years, and Group C 38 years ($p = 0.226$). The median body mass index (BMI) for all three groups was 22 ($p = 0.764$). The mean implant volumes for Group C (369 ml) was larger than those for Groups A and B (311 and 326 ml, respectively). But this was not statistically significant.

Complications

The incidence of total complications was 9.0% in 100 patients ($n = 9$). No complications occurred in Group C. Four (9.1%) out of 44 patients had complications in Group A. 5 (11.1%) out of 45 patients had complications in Group B. There was no difference in the occurrence of total complications between Groups A and B ($p>0.05$). All complications are summarized in Table 2.

Minor complications occurred in 6 (6.0%) patients. Among the 3 (6.8%) cases of minor complications in Group A, two (4.5%) developed lower extremity deep venous thrombosis (DVT), and one (2.3%) had an axillary incision infection. The remaining 3 cases occurred in Group B, 2 (4.4%) had

Table 1
Patient demographic date.

	Total (breasts) $N = 100$	Group A (ABPM-assisted IBBR) N(per)=44(44%)	Group B (LD-assisted IBBR) N(per)=45(45%)	Group C (Two-stage IBBR) N(per)=11(45%)	p
Right	54 (54.0%)	20 (45.5%)	30 (66.7%)	4 (36.4%)	0.061
Left	46 (46.0%)	24 (54.5%)	15 (33.3%)	7 (63.6%)	
IBBR with contralateral breast cosmetic surgery	20 (20.0%)	7 (15.9%)	10 (22.2%)	3 (27.3%)	0.343
Age, y	39.1 ± 9.2	37.5 ± 9.4	40.8 ± 9.1	38.2 ± 8.1	0.226
BMI	22.0 ± 3.5	21.7 ± 2.6	22.3 ± 4.5	22.3 ± 2.1	0.764
Hypertensive disease	1 (1.0%)	0	1 (2.2%)	0	–
Diabetes	1 (1.0%)	0	1 (2.2%)	0	–
Active smoking	5 (5.0%)	3 (6.8%)	2 (4.4%)	0	0.633
Previous non-breast surgical history	37 (37.0%)	16 (36.4%)	17 (37.8%)	4 (36.4%)	0.989
Previous breast surgical history	9 (9.0%)	4 (9.1%)	5 (11.1%)	0	0.513
NSM	–	42 (95.5%)	18 (40.0%)	–	$p<0.05$
SSM	–	2 (4.5%)	27 (60.0%)	–	$p<0.05$
modified radical mastectomy	–	–	–	11 (100%)	–
Chemotherapy	56 (56.0%)	23 (52.3%)	24 (53.3%)	9 (81.8%)	0.187
Radiotherapy	9 (9.0%)	3 (6.8%)	3 (6.7%)	3 (27.3%)	0.080
Implant volume (ml)	324.5 ± 94.5	311.5 ± 89.7	326.3 ± 90.9	369.1 ± 121.0	0.193
Follow up (months)	10.8 ± 3.2	11.0 ± 3.3	10.6 ± 3.1	11.0 ± 3.7	0.834

Table 2
Postoperative complications for IBBR.

	Total N(per)=9(9.0%)	Group A (ABPM-assisted IBBR) N(per)=4(9.1%)	Group B (LD-assisted IBBR) N(per)=5(11.1%)	$p = 0.973$	Group C (Two-stage IBBR) $N = 0$
Non-Breast complication	6 (6.0%)	3 (6.8%)	3 (6.7%)	0.627	0
LEDVT	4 (4.0%)	2 (4.5%)	2 (4.4%)	0.982	0
Metabolic acidosis	1 (1%)	0	1 (2.2%)	–	0
Infection*	1 (1%)	1 (2.3%)	0	–	0
Breast complication	5 (5.0%)	3 (6.8%)	2 (4.4%)	0.627	0
Hematoma	0	0	0	–	0
Seroma	0	0	0	–	0
Infection	0	0	0	–	0
Breast skin necrosis	3 (3.0%)	3 (6.8%)	0	–	0
Flap necrosis	1 (1.0%(	0	1 (2.2%)	–	0
Capsular contracture	1 (1.0%)	0	1 (2.2%)	–	0
Reoperation	4 (4.0%)	3 (6.8%)	1 (2.2%)	0.295	0
Implant removal	3 (3.0%)	2 (4.5%)	1 (2.2%)	0.544	0

* infection in axillary incision.

a DVT and one (2.2%) developed metabolic acidosis postoperatively ($p>0.05$). All patients recovered following appropriate treatment.

The rate of major complications was 5.0% ($n = 5$) for all the patients. No hematomas, seromas or infections were recorded in our patients. Four (4%) out of 100 breasts had flap necrosis after surgery, 3 (6.8%) were mastectomy flap necrosis which occurred in Group A and one skin island necrosis (2.22%) occurred in Group B. One case (2.2%) of grade III capsular contracture occurred 6 months after radiotherapy in Group B. No significant differences were noted between Groups A and B in terms of major complications ($p>0.05$). Reoperations for complications were performed on 4 (4.0%) patients. In Group

Table 3
Cost-effectiveness.

	Total N(per)=92(92.0%)	Group A (ABPM-assisted IBBR) N(per)=39(88.6%)	Group B (LD-assisted IBBR) N(per)=44(97.8%)	Group C (Two-stage IBBR) N(per)=9(81.8%)	*p*
Duration of surgery (min)	249.5 ± 78.2	191.7 ± 58.9[a]	310.8 ± 62.3[a,b]	229.0 ± 68.4[b]	$p<0.001$
Cost of hospitalization ($)	7815.9 ± 1138.9	8051.3 ± 849.2[a]	7566.0 ± 1172.7[a]	7896.5 ± 1762.2	$p = 0.128$

Groups with different superscript letter (a, b) are significantly different from each other.

Table 4
Results of BREAST-Q.

	Group A (ABPM-assisted IBBR) N(per)= 39 (88.6%)	Group B (LD-assisted IBBR) N(per)=44(97.8%)	Group C (Two-stage IBBR) N(per)=9(81.8%)	***p***
Satisfaction with breasts	73.2 ± 14.9	72.9 ± 13.5	80.6 ± 14.1	$p>0.05$
Satisfaction with outcome	96.6 ± 8.3ab	91.6 ± 16.2ac	100±0bc	$p<0.05$
Psychosocial well-being	92.6 ± 13.4	92.2 ± 12.7	90.9 ± 15.9	$p>0.05$
Sexual well-being	77.5 ± 24.9	60.2 ± 30.2	51.9 ± 31.7	$p>0.05$
Physical well-being	82.8 ± 18.0	82.8 ± 13.9	78.4 ± 15.7	$p>0.05$
Satisfaction with information	98.3 ± 4.3	96.8 ± 5.0	100±0	$p>0.05$
Satisfaction with surgeon	97.8 ± 9.6	98.1 ± 7.1	100±0	$p>0.05$
Satisfaction with medical staff	100±0	100±0	100±0	$p>0.05$

Groups with different superscript letter (a, b, c) are significantly different from each other.

A all reoperations ($n = 3$, 6.8%) were due to wound healing problems, 2 of which resulted in implant removal. In Group B one (2.2%) patient required reoperation for capsular contracture and change of implant.

Cost-effectiveness

The total mean duration of surgery was 249.5 ± 78.2 min. The mean duration of surgery in Group B(310.8 ± 62.3 min) was significantly longer than Group A (191.7 ± 58.9 min, $p<0.01$) and Group C (229.0 ± 68.4 min, $p<0.01$). But the duration of surgery between Groups A and C was not significantly different ($p>0.05$). The cost of hospitalization is shown in Table 3. The cost of hospitalization in Group A ($8051.3 ± 849.2) was significantly higher compared to Group B ($7566.0 ± 1172.7, $p<0.05$). But there was no statistically significant difference between Groups A and C ($7896.5 ± 1762.2, $p>0.05$).

Quality of life

The postoperative BREAST-Q was completed by 92 (92.0%) of 100 patients between 6 and 15 months with a mean duration of 11 months. Thirty-nine (88.6%) out of 44 patients in Group A, 44 (97.8%) out of 45 in Group Band 9 (81.8%) out of 11 patients in Group C completed a single questionnaire. It can be seen from the data in Table 4 that patients in Group C reported significantly more satisfaction with outcome than the other two groups ($p<0.05$). The mean postoperative score for satisfaction with breasts, psychosocial well-being, sexual well-being, physical well-being, satisfaction with information, surgeon and medical staff were not significantly different among the three groups ($p>0.05$).

Discussion

Dikmans et al. conducted a series of prospective randomized controlled trials and concluded that one-stage ADM-assisted IBBR was associated with a significantly higher risk of surgical complications, reoperation, and implant removal than two-stage IBBR.[7,9,10,17] One-stage ADM-assisted IBBR had similar results in terms of patient-reported QoL but had higher cost compared with two-stage IBBR.[7] In

our region, ABPM is less expensive than ADM, and therefore we sought to report our experiences with ABPM and to assess the postoperative outcomes (including complications and aesthetic effect) and cost-effectiveness between different implant-based reconstruction methods.

Our results are in accord with recent studies indicating that two-stage IBBR is a safe method.[18] In the prospective study by Dikmans et al., the rate of complications of ADM-assisted IBBR was higher than two-stage IBBR.[9] A retrospective study comparing ADM-assisted with LD-assisted IBBR, showed similar complication rates.[19] The complications of ADM-assisted IBBR ranged from 10 to 46%.[9,20–22] The differences in complication rates in these studies may be related to differences in the type of ADM used.[23] The complications of bovine ADM appear to be lower than those of human[21] and porcine derived ADMs.[24] Eichler et al. found no difference in complication rates with ABPM used in IBBR, when compared with bovine ADM.[15]

High BMI and smoking are considered to be risk factors for IBR. The mean age at diagnosis of breast cancer in China is 45–55 years, which is younger than western women.[25] In another of our studies, the median age of the breast cancer patients who underwent BR was 40 years, while the median BMI was 23 kg/m^2.[26] This suggests that Chinese women who choose BR surgery tend to be younger and have a lower BMI than western women.[25] In China fewer women (2.8%) smoke, especially younger women.[27] This may explain why our postoperative complication rate is lower than other similar studies.

In our study there was no difference in the complication rates between one-stage ABPM-assisted and LD-assisted IBBR ($p>0.05$). Minor complications were not associated with implant removal. One patient developed metabolic acidosis postoperatively in the LD-assisted IBBR group, which could be attributed to the longer surgical duration.[28] Major complications are the main reason for failure with IBBR.[6] ADM has been reported to increase the risk of seroma, which has been reported to occur on average in 6.5% of patients, ranging from 0 to 15.4%.[6,20] It is thought that perforated ADMs may reduce the incidence of seromas.[6,14] When using ABPM in IBBR, seromas and hematomas appeared in 15% and 3.75%, respectively.[14] The low occurrence of seromas and hematomas could be attributed to the porous structure of ABPM. Infection and mastectomy skin flap necrosis may result in implant loss.[29] According to relevant literature reports, the implant infection rate in IBBR ranges between 0.2 and 35.8%.[8] Our data demonstrates that ABPM-assisted IBBR or LD-assisted IBBR did not increase the risk of infection compared with two-stage IBBR. We used two doses of intravenous antibiotics peri–operatively, which we found effective in preventing surgical site infection.

Mastectomy flap necrosis rates in breast reconstruction with ADMs range from 4.3% to 34.2%,[6,14] whereas it occurred at an average rate of 5.4% when an ABPM was used.[16] Our data showed ABPM-assisted IBBR had the highest rate of flap necrosis (6.8%), which is similar to current literature reports. We found that all flap necrosis was within the vicinity of the incision. The variation in postoperative complication rates has been correlated with a learning curve.[9]

The incidence of capsular contracture with ADM use varies greatly in the literature (0.4–8.1%).[6] ADM may reduce the inflammatory response after implantation and the subsequent risk of capsular contracture.[6] Pre- or postoperative radiotherapy can increase the complication rate including the rate of capsular contracture.[23] However, it has been proposed that the effect of radiotherapy on capsular contracture can be reduced after using ADM in both animals[30, 31] and human subjects.[32] Lardi et al. reported similar rates of capsular contracture in non-irradiated and irradiated breasts (6% vs 13%) when ADMs were used.[32]

Implant loss is the most serious event in IBBR.[22] It incurs financial loss and psychological trauma for patients, and can affect confidence in reoperation.[33] Implant loss in ADM-assisted IBBR ranges from 4.9 to 29%.[9,21,23,24] When used with ABPM implant loss has been reported as ranging from 3.7 to 4.2%.[12,15,16] The complication rate and implant loss observed in our study was lower than the reported range. In our study only 3 patients using ABPM received radiotherapy. However, it is not possible to draw any conclusions due to the small sample size and short follow-up. The role of ABPM in radiotherapy still requires further investigation. In general, it is accepted that co-morbidities such as a BMI>30, a smoking history, and radiotherapy are risk factors for implant loss.[33]

The way in which healthcare is financed differs considerably between countries, so we calculated the cost in patient admission hospital cost for each patient . WE recorded the data for duration of operation to enable comparison with other studies. Minimizing the duration of surgery is important

for controlling cost.[10] Our results show that the LD-assisted IBBR group had the longest duration of surgery (310.8 ± 62.3 min). The total duration of operative time for one-stage IBBR with ADM and two-stage IBBR are similar and consistent across the literature.[10] However, two-stage IBBR requires two operations at least s, and multiple expansions visits to the outpatient clinic. This also increases the hidden economic burden for patients. ABPM-assisted IBBR demonstrated superior efficiency in terms of operation duration compared with the other two traditional reconstruction methods.

Cost is an important factor in the choice of prosthetic materials and methods of breast reconstruction used.[6] The cost of ADMs varies between $1825 and $4856.[34] Negenborn et al. showed that the total direct cost for unilateral ADM-assisted IBBR was approximately $13,012; whereas two-stage IBBR cost reached $9965.[10] However, in the UK the cost of IBBR with ADM is less than two-stage IBBR.[20] The reasons for cost differences include the cost of materials, length of surgery, hospital re admission for complications etc. ABPM has an economic advantage over ADM.[15] ABPM of the same size is 25% less expensive ($28.00/cm2 vs $37.10 /cm2).[16] In our study, ABPM-assisted IBBR did not increase the total cost compared with two-staged IBBR.

Health outcomes are an important factor in assessing the utility of an operation.[10] The BREAST-Q is a subjective method reflecting patients' satisfaction after breast reconstruction.[7] Most authors report that using ADM can achieve a good aesthetic outcome.[6] In the article by Negenborn et al. the aesthetic results and health outcomes were similar between one-stage IBBR with ADM and two-stage IBBR when measured using the BREAST-Q.[7] Similar findings were also reported with the EQ-5D-5 L questionnaire.[10] However, autologous breast reconstructions usually report better satisfaction rates.[35] One study reported that the cosmetic outcomes of LD-assisted IBBR were better than ADM-assisted IBBR.[19] But the outcome of ABPM in IBBR compared favorably with ADMs.[15] In our study, all three groups were scored above 90 demonstrating satisfactory results. This study appears to confirm that QoL scores in those undergoing IBBR with ABPM was no less than two-stage IBBR.

However, our study has limitations. It was a retrospective case series. The adverse events were few which makes statistical analysis difficult. Another limitation is that patients did no complete a preoperative BREAST-Q. Finally, Follow-up was too short to assess possible differences in long term outcomes. Future studies will be needed to address these issues. However, from this study we can obtain some helpful conclusions.

Conclusion

The authors present a multisurgeon, retrospective study of ABPM use in immediate IBBR through comprehensive comparison of complications, cost-effectiveness and quality of life (QoL) with other methods. To date, it is the largest study of IBBR with ABPM. On the basis of our results, ABPM is a safe and convenient option for IBBR, producing overall patient satisfaction when compared with other IBBR procedures. By using ABPM we not only maintained a low rate of complications, but we also reduced the duration of surgery compared to LD and TE. Furthermore, although slightly more expensive than LD, ABPM did not increase the costs compared to two-stage IBBR. The selection of suitable patients is an issue of great importance to reduce implant loss rates following IBBR with ABPM.

Declaration of Competing Interest

The authors declare that they have no conflict of interest.

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Ethical approval

Ethical approval to undertake this study was examined from Human Research Ethics Committee, Tianjin Medical University Cancer Institute and Hospital (BC2017024).

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