



Making an informed choice: Which breast reconstruction type has the lowest complication rate?



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ABSTRACT

Introduction: The aim of this study was to investigate long-term breast reconstruction outcomes at a single institution in order to offer data-driven counseling for patients.

Methods: A retrospective review was performed of 399 patients who underwent mastectomy with 1-stage implant-based breast reconstruction (IBBR), 2-stage IBBR, or autologous tissue reconstruction (ATR) for invasive breast cancer or ductal carcinoma in situ at our institution from 2010 to 2017. Complications were classified as major for any unplanned return to the operating room (OR).

Results: Overall complication rates were similar among 1-stage IBBR (59%), 2-stage IBBR (60%), and ATR (52%, $p = 0.54$). Factors independently associated with major complications were diabetes (OR = 25.4 95% CI: 3.2–202.4; $p = 0.002$), and 1-stage IBBR vs. ATR (1-stage: OR = 2.0 95% CI: 1.0–4.0; $p = 0.04$). Bilateral procedures were also at increased risk of major complications on univariate analysis (OR = 1.59 95% CI: 1.0–2.5; $p = 0.04$).

Conclusions: Long-term breast reconstruction complication rates are higher than previously anticipated. Patients should be counseled that IBBR is associated with higher rates of complications, including unplanned return to the OR, compared to ATR.

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Introduction

Many women who need or choose mastectomy as treatment for their breast cancer have the option for reconstruction. Several reconstructive options exist today, broadly categorized into implant-based breast reconstruction (IBBR) or autologous tissue reconstruction (ATR). IBBR can be achieved in one stage (direct to implant) or two stages (tissue expander placement followed by expansion and then implant reconstruction at a second operation). ATR uses the patient's own tissue to reconstruct the breast using a deep inferior epigastric perforator (DIEP) flap, transverse rectus abdominis muscle/myocutaneous (TRAM) flap, latissimus dorsi myocutaneous flap, or superficial inferior epigastric artery (SIEA) flap.

A thorough discussion of the risks and benefits of each reconstructive option is an important component of the preoperative plastic surgery consultation. Knowing the risk of complications associated with each approach can help guide shared decision-making discussions. However, the available data on comparative risks among surgical approaches is inconsistent and often limited to short-term follow up.^{1–3} A recent randomized controlled trial demonstrated increased risk of surgical complications, reoperation, and removal of implants for 1-stage IBBR with acellular dermal matrices compared to 2-stage IBBR.⁴ Other prospective studies report higher complication rates, including return to the operating room, for ATR compared to IBBR⁵ and no difference in complications between 1- and 2-stage IBBR.⁶ Multiple studies have examined whether there is an increased rate of complications associated with certain comorbidities^{7,8} or the use of perioperative radiation therapy.^{9,10} However, there is a paucity of data directly comparing 1-stage IBBR vs. 2-stage IBBR vs. ATR with long-term follow up that could assist patients during preoperative consultation. Therefore,

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the aim of our study was to investigate the outcomes of 1-stage IBBR, 2-stage IBBR, and ATR at our institution to better guide pre-operative shared decision making.

Material and methods

A retrospective review was performed of a prospectively collected single-institution database of women who underwent mastectomy with immediate reconstruction using 1-stage IBBR, 2-stage IBBR, or ATR for invasive breast cancer or ductal carcinoma in situ (DCIS) between 2010 and 2017. The choice between 1-stage and 2-stage IBBR was at the discretion of the reconstructive surgeon and patient. Patient demographics, co-morbidities (smoking status, diabetes, use of anticoagulation, cardiac or pulmonary disease, and history of solid organ transplant) and tumor factors were analyzed. Smoking status was defined as active smoking during initial surgical consultation. Prior to reconstruction, patients were required to comply with smoking cessation which was confirmed preoperatively with a nicotine level assay. Tumor factors analyzed included histology, grade, and stage. Treatment factors of neoadjuvant/ adjuvant systemic therapy and radiation therapy were reviewed. Complications examined included capsular contracture, infection, seroma, hematoma, wound breakdown, mastectomy flap ischemia, and nipple complications for those undergoing nipple-sparing mastectomy. Any complication requiring an unplanned return to the operating room (OR) was classified as a major complication, while complications managed non-operatively were classified as minor complications.

Patient demographics and tumor characteristics were compared using analysis of variance (ANOVA), chi-square or Fisher's exact test. Logistic regression was used to model risk factors associated with total and major complication rates at the patient level. Additionally, generalized estimating equations were used to examine major complications using each breast operated on as the unit of analysis. Two-sided p-values <0.05 were considered statistically significant. SAS version 9.4 (SAS Institute, Cary, NC) was used for analysis.

Results

Patient characteristics

A total of 399 mastectomy patients underwent reconstruction during the study period. Mean age at first operation was 51.9 years (range 22–82). IBBR patients were younger than ATR patients on

average (1-stage IBBR 50.9 years, 2-stage IBBR 51.5 years, ATR 55.9 years; $p = 0.007$). Patients undergoing ATR were more likely to be postmenopausal and had higher BMI. Patients undergoing 2-stage IBBR were more likely than 1-stage IBBR and ATR patients to be smokers (7% vs. 2% and 2%; $p = 0.03$); otherwise there were no significant differences in comorbidities among the groups (Table 1). Median follow-up was 1.9 years (range 0.1–7.6 years).

Treatment characteristics

Among the groups, there was no significant difference in mean tumor grade, size or final pathologic stage. Twenty-four percent of patients underwent neoadjuvant systemic therapy with no significant differences among the groups ($p = 0.67$). A total of 51% of patients received adjuvant endocrine therapy and 24% received adjuvant cytotoxic therapy, again with no significant differences among groups. Adjuvant radiation therapy was performed in 18% overall, and this adjuvant therapy did not significantly differ among the three groups (Table 2).

Surgery characteristics

All patients underwent mastectomy with immediate reconstruction. A majority, 68%, underwent bilateral procedures. Unilateral procedures were more common in patients undergoing ATR (47%) compared to 1-stage (31%) and 2-stage (29%) IBBR ($p = 0.03$). One-stage IBBR was performed in 193 (48%), 2-stage in 146 (37%) and ATR in 60 (15%) patients. Of patients who underwent ATR, DIEP flaps were most commonly performed ($n = 39$, 65%), followed by latissimus dorsi flaps in 11 (18%) and muscle sparing free transverse rectus abdominis myocutaneous (TRAM) flaps in 10 (17%). Mastectomy type varied among the groups, with nipple-sparing mastectomy most commonly performed in 1-stage IBBR patients (64%), followed by 2-stage IBBR (57%) and ATR (43%, $p < 0.01$). Skin-sparing mastectomy was most common in only ATR (48%). Acellular dermal matrix was used more in 2-stage (90%) compared to 1-stage IBBR (76%, $p < 0.001$). Implants were placed submuscular in 99% of 2-stage IBBR and 77% in 1-stage IBBR ($p < 0.001$). Axillary staging procedures did not significantly differ among the three groups with the majority (70%) undergoing sentinel lymph node biopsy at the first operation (Table 3).

Complications

Overall complication rates were similar among 1-stage IBBR

Table 1
Patient characteristics.

	1-Stage IBBR (n = 193)	2-Stage IBBR (n = 146)	ATR (n = 60)	Total (n = 399)	p value
Age, mean (SD)	50.9 (11.0)	51.5 (11.3)	55.9 (7.8)	51.9 (10.8)	0.007
Postmenopausal (%)	90 (47)	70 (48)	47 (78)	207 (52)	<0.001
Race/Ethnicity (%)					0.22
White	165 (86)	127 (87)	46 (77)	338 (85)	
Black	5 (3)	2 (1)	4 (7)	11 (3)	
Hispanic	10 (5)	13 (9)	6 (10)	29 (7)	
Asian/Pacific Islander	12 (6)	4 (3)	4 (7)	20 (5)	
Other	1 (1)	0 (0)	0 (0)	1 (0)	
BMI (SD)	25.0 (5.0)	25.4 (5.1)	29.6 (5.6)	25.8 (5.4)	<0.001
Current smoker (%)	3 (2)	10 (7)	1 (2)	14 (4)	0.03
Diabetes, percent	5 (3)	4 (3)	4 (7)	13 (3)	0.29
Anticoagulation (%)	1 (1)	1 (1)	1 (2)	3 (1)	0.55
Severe cardiac disease (%)	1 (1)	2 (1)	0 (0)	3 (1)	0.74
Severe pulmonary disease (%)	1 (1)	1 (1)	1 (2)	3 (1)	0.55
Collagen vascular disorder (%)	0 (0)	1 (1)	0 (0)	1 (0)	0.52

Table 2
Tumor and treatment characteristics.

	1-Stage IBBR (n = 193)	2-Stage IBBR (n = 146)	ATR (n = 60)	Total (n = 399)	p value
Grade (%)					0.16
Missing	5	3	1	9	
1 Low	30 (16)	32 (22)	14 (24)	76 (20)	
2 Intermediate	81 (43)	57 (40)	16 (27)	154 (40)	
3 High	77 (41)	54 (38)	29 (49)	160 (41)	
Tumor size, cm					0.21
Mean (SD)	2.6 (2.3)	2.7 (2.3)	2.1 (1.8)	2.6 (2.2)	
Final stage (%)					0.64
Missing/DCIS	40	29	15	84	
I	77 (50)	49 (42)	22 (49)	148 (47)	
II	52 (34)	52 (44)	15 (33)	119 (38)	
III	20 (13)	14 (12)	6 (13)	40 (13)	
IV	4 (3)	2 (2)	2 (4)	8 (3)	
Neoadjuvant Therapy (%)					0.67
Yes	45 (23)	39 (27)	13 (22)	97 (24)	
No	148 (77)	107 (73)	47 (78)	302 (76)	
Adjuvant Endocrine Therapy (%)					0.26
Yes	103 (53)	77 (53)	25 (42)	205 (51)	
No	90 (47)	69 (47)	35 (58)	194 (49)	
Adjuvant Cytotoxic Chemotherapy (%)					0.73
Yes	46 (24)	34 (23)	17 (28)	97 (24)	
No	147 (76)	112 (77)	43 (72)	302 (76)	
Radiation Therapy (%)					0.36
Yes	33 (17)	31 (21)	8 (13)	72 (18)	
No	160 (83)	115 (79)	52 (87)	327 (82)	

Table 3
Surgery characteristics.

	1-Stage IBBR (n = 193)	2-Stage IBBR (n = 146)	ATR (n = 60)	Total (n = 399)	p value
Bilateral procedure (%)	134 (69)	104 (71)	32 (53)	270 (68)	0.03
Mastectomy Procedure (%)					0.01
Standard	2 (1)	7 (5)	5 (8)	14 (4)	
Nipple-Sparing	123 (64)	83 (57)	26 (43)	231 (58)	
Skin-Sparing	68 (35)	56 (38)	29 (48)	153 (38)	
Acellular Dermal Matrix Used (%)	145 (76)	132 (90)	NA	277 (82)	<0.001
Implant Placement (%)					<0.001
Submuscular	148 (77)	144 (99)	NA	291 (86)	
Subcutaneous	45 (23)	2 (1)	NA	47 (14)	
Axillary Staging (%)					0.09
Axillary Lymph Node Dissection (ALND)	9 (5)	11 (8)	7 (12)	27 (7)	
Sentinel Lymph Node Biopsy (SLNB)	145 (75)	97 (66)	37 (62)	279 (70)	
None	14 (7)	11 (8)	9 (15)	34 (9)	
SLNB with completion ALND	25 (13)	27 (19)	7 (12)	59 (15)	

NA = not applicable.

(59%), 2-stage IBBR (60%), and ATR groups (52%, $p = 0.54$). There were no significant differences in either major or minor complication rates between the three groups when analyzed separately ($p = 0.16$ and $p = 0.63$). However, when comparing all IBBR patients to ATR patients, IBBR patients were more likely to experience a major complication requiring return to the OR, approaching significance (41% IBBR, 28% ATR; $p = 0.06$). Implant loss was not different between 1-stage (21%) and 2-stage IBBR (20%, $p = 0.76$). There were no differences between IBBR and ATR in seroma rates, wound breakdown or mastectomy flap ischemia (Table 4). While IBBR patients were more likely to undergo skin and nipple-sparing mastectomies, there was no difference in overall complication rates between the nipple and skin sparing mastectomy versus non-nipple-sparing approach (62% vs. 37%; $p = 0.28$).

On pooled analyses of complications, certain comorbidities were associated with specific complication outcomes. Wound breakdown was more common in smokers ($p = 0.045$) and mastectomy flap ischemia more common in diabetics ($p < 0.001$). On multivariable analysis (per patient analysis), diabetes was the one comorbidity associated with an overall higher likelihood of having a major

complication (OR = 24.1 95% CI: 3.0–191.6; $p = 0.003$). Patients undergoing bilateral mastectomy were also at higher risk for major complications (OR = 1.59 95% CI: 1.0–2.5; $p = 0.04$). One-stage IBBR was associated with an overall higher complication outcome compared to ATR (OR = 2.2 95% CI: 1.1–4.2, $p = 0.02$ (Table 5A). Similar results were seen when the analysis was conducted using breast as the unit of analysis as diabetes (OR = 5.58; 95% CI 2.56–12.18; $p < 0.001$) and 1-stage (OR = 1.95; 95% CI: 1.05–3.62; $p = 0.03$) were significant on multivariable analysis ((Table 5B).

Discussion

An informed discussion about breast reconstruction options is important, particularly as more women choose to undergo bilateral mastectomies with reconstruction for breast cancer prophylaxis or treatment. We found high long-term complication rates among our surgical population overall, including higher rates of reoperation after IBBR compared to ATR. There was no difference in reoperation rates found between 1- and 2-stage IBBR techniques. Surgical complication rates for IBBR in the literature range from 5 to

Table 4
Complications.

	1-Stage IBBR (n = 193)	2-Stage IBBR (n = 146)	ATR (n = 60)	All IBBR (n = 339)	Total (n = 399)	p value
Overall Patient Complication Rate (%)	114 (59)	87 (60)	31 (52)	201 (59)	232 (58)	0.54
Major Complications (%)	81 (42)	58 (40)	17 (28)	139 (41)	156 (39)	0.16
Minor Complications (%)	32 (17)	28 (19)	13 (22)	60 (18)	73 (18)	0.63
Hematoma (%)	22 (11)	12 (8)	2 (3)	34 (10)	36 (9)	0.16
Return to OR (%)	21/22 (95)	9/12 (75)	2/2 (100)	30/34 (88)	32/36 (89)	
Seroma (%)	26 (14)	19 (13)	8 (13)	45 (13)	53 (13)	0.99
Return to OR (%)	8/26 (31)	5/19 (28)	5/8 (63)	13/45 (29)	18/53 (34)	
Wound Breakdown (%)	15 (8)	19 (13)	7 (12)	34 (10)	41 (10)	0.26
Return to OR (%)	10/15 (71)	14/19 (74)	3/7 (43)	24/34 (71)	27/41 (66)	
Mastectomy Flap Ischemia (%)	30 (16)	18 (12)	9 (15)	48 (14)	57 (14)	0.69
Return to OR (%)	27/30 (90)	16/18 (89)	6/9 (67)	43/48 (90)	49/57 (86)	
Infection (%)	19 (10)	23 (16)	6 (10)	42 (12)	48 (12)	0.22
Return to OR (%)	14/19 (74)	19/23 (83)	4/6 (67)	33/42 (79)	37/48 (77)	
Nipple complications, nipple-sparing (%)	22 (11)	18 (12)	7 (12)	40 (12)	47 (12)	0.97
Return to OR (%)	7/22 (32)	8/18 (44)	1/7 (14)	15/40 (38)	16/47 (34)	
Implant/Expander Removal	41 (21)	29 (20)	NA	70 (21)	70 (18)	

p value displayed for 1-stage vs. 2-stage vs. ATR.

Table 5a

Univariate and multivariable analysis of patient and tumor characteristics associated with major complications (Patient level analysis, n = 399).

	Univariate		Adjusted Model	
	Odds Ratio	p value	Odds Ratio	p value
Age	1.0 (0.97–1.01)	0.41		
BMI	0.99 (0.95–1.03)	0.55		
1-Stage IBBR vs. ATR	1.8 (0.97–3.43)	0.06	2.03 (1.03–3.98)	0.042
2-Stage IBBR vs. ATR	1.7 (0.87–3.20)	0.12	1.81 (0.90–3.64)	0.096
Bilateral Procedure	1.59 (1.02–2.48)	0.04	1.59 (1.00–2.51)	0.05
Diabetes	20.17 (2.59–156.70)	0.004	1.81 (0.90–3.64)	0.0023
Smoker	2.91 (0.96–8.86)	0.06		
Neoadjuvant Therapy	1.26 (0.79–2.00)	0.33		
Radiation Therapy	1.50 (0.90–2.51)	0.12		
Chemotherapy	0.89 (0.56–1.44)	0.64		

Table 5b

Univariate and multivariable analysis of patient and tumor characteristics associated with major complications (Breast unit level analysis, n = 669).

	Univariate		Adjusted Model	
	Odds Ratio	p value	Odds Ratio	p value
Age	1.00 (0.98–1.02)	0.95		
BMI	1.00 (0.95–1.03)	0.63		
1-Stage IBBR vs. ATR	1.76 (0.96–3.23)	0.07	1.95 (1.05–3.62)	0.03
2-Stage IBBR vs. ATR	1.51 (0.81–2.82)	0.20	1.67 (0.88–3.16)	0.12
Diabetes	4.97 (2.36–10.44)	<0.001	5.58 (2.56–12.18)	<0.001
Smoker	2.19 (0.90–5.34)	0.09		
Neoadjuvant Therapy	1.07 (0.70–1.64)	0.74		
Radiation Therapy	1.30 (0.82–2.06)	0.27		
Chemotherapy	0.91 (0.58–1.43)	0.69		

63.9%^{4,6,11–16} and 4–33% for ATR.^{5,17–19} This wide range of complication rates is likely a reflection of variation in study design, patient population, inclusion criteria for complication definition, and length of follow-up.

Data analyzing postoperative outcomes between IBBR and ATR vary. A multicenter study by Mastectomy Reconstruction Outcomes Consortium (MROC) showed higher rates of major complications in ATR compared to implant/expander reconstructions.³ However, postoperative complications were limited to one-year follow up. Other national pooled data analyses showed immediate IBBR is not associated with an increase in overall 30-day complication risk, however certain wound complications may be higher in patients undergoing staged IBBR with tissue expanders.² Similarly to the MROC, Bennett et al., demonstrated a higher rate of re-operative complications following non-latissimus dorsi ATR techniques

compared to IBBR.⁵ Contrary to this, Lagares-Borrego et al. found significantly lower surgical complication rates following DIEP reconstruction compared to 2-stage IBBR.¹⁷ A systematic review of 14 observational studies comparing IBBR to ATR techniques reported a higher relative risk of reconstructive failure and skin or flap necrosis in ATR.²⁰ In a study examining outcomes between ATR and IBBR for prophylactic mastectomy, on the per-breast analysis, ATR had a lower complication rate – perhaps indicating ATR's intermittently suggested increased complication risk is only when completed for therapeutic mastectomy.²¹ Given this confusing picture, it was important for our preoperative breast surgery consultations to have further data examining all three major options for reconstruction with long-term outcomes.

In this present study, data was derived from a prospectively maintained database with follow up times allowing for inclusion of

both short term and long term complications. Many of the prior studies comparing breast reconstruction techniques have analyzed larger national databases or multi-institutional collaborative datasets with complication follow up times limited to 30 days or one year. These databases do not account for longer-term complications such as delayed need for implant removal or replacement and could explain why our study, with a follow up of 7.6 years, has both higher overall complication rates, as well as a higher complication rate seen in the IBBR group versus the ATR population.

While our data shows higher major complication rates for IBBR compared to ATR, there was no significant difference found between 1-stage and 2-stage IBBR in overall or major complications, which differs from a previously published trial supporting a higher risk of surgical complications in 1-stage IBBR compared to 2-stage.⁴ Additionally, while the most common complication requiring return to the OR for all patients was mastectomy flap ischemia, this complication did not differ between patients who underwent nipple-sparing versus non nipple-sparing mastectomy for flap creation for anticipated reconstruction.

While objective data on skin flap perfusion is routinely used during ATR at our institution, the current practice for IBBR is clinical evaluation of mastectomy skin flaps. The use of more objective data, such as indocyanine green (ICG) angiography has been suggested to decrease rates of complications associated with mastectomy skin ischemia as early as 1999.²² However, ICG angiography has only recently gained popularity over the more traditional models to assess mastectomy flap tissue perfusion as the breast surgical community has trended towards increasing rates of skin and nipple-sparing mastectomy with reconstruction.²³ Recent systematic review and meta-analysis has shown its benefit, especially in implant-based reconstruction.²⁴ While this recent review is limited to single-institution and small sample size data pooled for meta-analysis, the early data is telling. We previously have used the more traditional model of clinical assessment for implant-based reconstruction and just recently have started to use ICG angiography for intraoperative planning during ATR cases. However, a benefit of this single-institution review of a prospectively maintained database is the opportunity for internal quality assurance and quality improvement in addition to answering broader research questions.^{25,26}

On multivariable analysis, diabetes was the only predictive comorbidity of major complications in all patients, underscoring the importance of perioperative glucose management. In particular mastectomy flap ischemia was found in subset analysis to be more common in diabetics, and this was the most common reason for return to the OR. While other studies have reported a negative impact on reconstructive complications associated with smoking history,^{2,6} history of or adjuvant radiotherapy,^{3,5,6,9,10,27,28} obesity²⁹ and bilateral over unilateral mastectomy, we did not find this in our retrospective review.^{3,30} This could be secondary to a difference in our population's rates of obesity, smoking, and/or type and duration of radiotherapy compared to the prior studies.

Bilateral mastectomy was also a notable variable on multivariable analysis as an increased risk for complications. There were more women with bilateral mastectomies in the implant group and these women did have an increased risk of complications as did all women with implant based reconstructions compared to tissue reconstruction. This is consistent with prior literature which shows an increased risk of surgical site complications in patients undergoing bilateral mastectomy compared to unilateral mastectomy, specifically with worse 30-day postoperative outcomes in bilateral compared to unilateral IBBR.^{11,30} Given bilateral mastectomies are also associated with increased healthcare costs, patients should be appropriately counseled on the increased risks of complications and potential increased emergency department visits

postoperatively prior to making an informed decision.³¹

By comparing outcomes for all three of the major techniques for post-mastectomy reconstruction (1-stage IBBR, 2-stage IBBR and ATR), this study can help inform the preoperative breast surgery discussion. While many studies compare a subset of these techniques, few have compared all three categories. Additionally, many prior studies of post-mastectomy reconstruction complications involve large national databases, which are often subject to missing data and lack of long-term follow up. While frequent prior data has reported lower complication rates overall and lower rates of unplanned return to the operating room, these studies do not take into account long-term unplanned operative needs such as implant removal or replacement or delayed flap revision. In addition, within post-mastectomy reconstruction, there is substantial variation in surgical techniques, patient selection, tumor and treatment characteristics that may create a confusing story for our patients during the preoperative discussion. This study closely examines surgical techniques, baseline patient and tumor characteristics, and reconstruction methodologies so our patient population can make a more informed choice based on our institutional outcomes.

Our study has several limitations including those inherent to a single-institution retrospective review. The data also lacks information regarding overall costs to the patient and hospital, making cost-effectiveness decisions difficult. It also does not assess post-operative quality of life indicators to help patients decide which reconstruction option is not just safest, but will make them the happiest postoperatively. Future studies are needed to examine the impact of these factors to facilitate a more informed choice following preoperative counseling.

Conclusions

Reconstruction after mastectomy can be an important component of breast cancer care. However, patients should be aware that it is associated with high long-term complication rates and those complication rates are increased in bilateral versus unilateral procedures. Many factors should be taken into consideration when counseling patients on post-mastectomy reconstruction options, including patient co-morbidity profile, immediate and long-term complication rates and desired cosmetic outcomes. Patients should be counseled on the higher rates of operative complications associated with IBBR. To decrease postoperative complications, regardless of reconstruction type, diabetes management should be optimized in all patients undergoing post-mastectomy reconstruction.

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Declaration of competing interest

The authors of the submission "Making an Informed Choice: Which Breast Reconstruction Type Has the Lowest Complication Rate?" (Patrick T. Hangge, Kristen Jogerst, Ahmed Mohsen, Heidi E. Kosiorek, Patricia A. Cronin, Chee-Chee H. Stucky, Nabil Wasif, Richard J. Gray, Alanna M. Rebecca, William J. Casey, III, Barbara A. Pockaj) have no financial or personal relationships with people or organizations that could inappropriately influence this work.

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Appendix A. Supplementary data

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