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Breast

Clinical and Healthcare Resource Use Outcomes between Dual-plane and Prepectoral Techniques in Implant-based Breast Reconstruction: A Multicenter Retrospective Study

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Background: This multicenter, retrospective study compared clinical outcomes and healthcare resource use in patients who underwent dual-plane (DP) or prepectoral (PP) implant-based breast reconstruction (IBR) after mastectomy in the United States.

Methods: Medical records were selected for patients at five sites undergoing immediate one-stage direct-to-implant (first hospitalization) or two-stage IBR (first and second hospitalization) using either DP or PP. Inverse probability of treatment weighting was used to adjust for potential confounders. Complications and healthcare resource use were assessed with logistic regression; pain severity was assessed with ordinary least-squares regression.

Results: After inverse probability of treatment weighting, data from 255 patients (DP = 130, PP = 125) and 441 breasts (DP = 226, PP = 215) were analyzed. Mean pain severity scores were lower with PP versus DP immediately after IBR for first ($P = 0.0002$) and second hospitalizations ($P = 0.0145$), and before discharge for first ($P < 0.0001$) and second hospitalizations ($P = 0.0002$). A greater proportion of PP versus DP patients had a shorter hospital length of stay (≤ 23 hours) for first hospitalization ($P = 0.0052$); proportions were similar for second hospitalization ($P = 0.5499$). Intravenous narcotics were prescribed less frequently to PP versus DP patients during first (61.1% versus 69.8%, respectively; $P = 0.1486$) and second (37.5% versus 55.3%, respectively; $P = 0.0172$) hospitalizations. Complication rates were low in both groups after first hospitalization discharge (DP: 13.6%, PP: 12.5%, $P = 0.7225$).

Conclusion: This retrospective study suggests that the PP technique in IBR may offer benefits related to clinical outcomes and health resource utilization; however, larger studies, including randomized controlled trials, are needed to confirm.

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INTRODUCTION

Among women in the United States, breast cancer is the most commonly diagnosed cancer, accounting for 276,480 (30%) of the 912,930 estimated new cases of female cancer in 2020.[1] Approximately one-third of women diagnosed with early breast cancer (stages I and II) and over two-thirds of women diagnosed with stage III breast cancer received surgical treatment with mastectomy in 2016.[2] Breast reconstruction is an option for many women after mastectomy, and procedures for reconstruction may use breast implants, autologous tissue, or both.[3] An Agency for Healthcare Research and Quality analysis of hospital-inpatient and hospital-based ambulatory surgery settings in 22 US states found that from 2009 to 2014, the rate of breast reconstruction after mastectomy increased from 21.7 to 35.1 per 100,000 (62%) among women aged 18 years and older.[4] The most recent data from the American Society of Plastic Surgeons indicate that in 2019 in the United States, 107,238 breast reconstruction procedures were performed; 88,005 (approximately 82%) of those procedures were implant-based reconstruction (IBR) procedures, and 65,971 (approximately 75%) of the IBR procedures involved use of an acellular dermal matrix (ADM).[5]

The dual-plane (DP) and prepectoral (PP) techniques are commonly used for IBR.[6] The DP technique involves partial placement of the implant under the pectoralis major muscle with use of ADM for support at the lower pole, whereas the PP technique involves placement of the implant above the pectoralis major muscle with use of ADM to cover and create a pocket for the implant.[6–12] Complications of the DP technique are largely related to the manipulation of the pectoralis muscle required with this method, and include pain, muscle functional impairment, spasm, and animation deformity. Because the PP technique does not involve pectoralis muscle manipulation, it has the potential for less pain and fewer complications, and implant placement above the muscle allows for a more natural appearance.[6,7,9,12] These advantages, coupled with advances in surgical techniques, may be contributing to a shift from use of the DP technique to use of the PP technique for IBR.[6,7,10,13] A potential limitation of the PP technique, however, is the presence of inadequate soft tissue support in some patients, increasing risks for rippling, wrinkling, or delayed healing.[7] Nonetheless, the research directly comparing the DP and PP techniques is mainly derived from small, single-center studies, and long-term outcomes of the PP technique are few, owing to its relatively recent introduction.[6,7,9] The objective of this study was to compare clinical outcomes and healthcare resource use (HRU) for up to 12 months between the DP and PP techniques in US patients who underwent immediate IBR across five surgical sites after mastectomy for breast cancer.

Takeaways

Question: What are the key differences in clinical outcomes and healthcare resource use between patients who underwent dual-plane (DP) versus prepectoral (PP) implant-based reconstruction after mastectomy?

Findings: This multicenter, observational, retrospective study showed that patients who underwent PP implant-based reconstruction had statistically significantly lower pain severity and shorter hospital length of stay than DP patients. Intravenous narcotics were also less frequently prescribed to PP versus DP patients. Complication rates after discharge were low in both groups.

Meaning: The PP technique in implant-based reconstruction may offer advantages related to clinical outcomes and healthcare resource use compared with the DP technique.

METHODS

Study Design

This was a multicenter, observational, retrospective analysis of the medical records of patients who had undergone immediate direct-to-implant or two-stage IBR procedures with an ADM (AlloDerm Regenerative Tissue Matrix, Allergan Aesthetics, an AbbVie company, Irvine, CA) between October 1, 2012 and March 1, 2018 at one of five US surgical practices representing both private and large institutional academic practices. These sites had used both DP and PP techniques for IBR at the time of the analysis, all of which had transitioned from DP to routine use of PP IBR procedures. Exact study periods were specific to each site and defined separately for DP and PP groups, based on the time periods when the site predominantly used the DP or PP techniques. At each site, patient medical records were searched to identify the most recent IBR conducted with each technique. Cases were accumulated by working backward from that point; the overlap period during which both techniques were performed was excluded to circumvent any learning curve effect or confounding between techniques. Patients meeting eligibility criteria were categorized into DP and PP groups for analysis. The study was reviewed and granted exemption status by a central institutional review board (Western Institutional Review Board, Puyallup, Wa.) or by a site's own institutional review board, as required.

Patients

Medical records were reviewed to identify female patients aged between 18 and 75 years who had undergone immediate unilateral or bilateral direct-to-implant or two-stage IBR with either the DP or PP technique and who had at least 3 months of follow-up at the site since the IBR. Patients were included if ADM was used in the IBR. If a bilateral mastectomy with immediate IBR on both sides was performed, patients who underwent the same procedural approach (direct-to-implant or two-stage) for both breasts were included. Pectoral blocks were allowed at the discretion of the surgeon. Patients were excluded for the following reasons at the time of IBR: advanced cancer (stages III and IV) and/or deep tumors (chest wall involvement), axillary dissection, poorly perfused flaps, body mass index of 35 kg/m^2 or more, diabetes with hemoglobin A1c greater than 7.5%, and compromised wound healing. Also excluded were patients who had undergone

a previous breast reconstruction procedure and patients who had an expander-plus-flap procedure in the first stage and flap reconstruction in the second stage (for two-stage procedures). Active or recent smokers (within 6 weeks before IBR) and patients who had received narcotics for other conditions before IBR were also excluded.

Data

Baseline and clinical characteristics, clinical outcomes, and HRU outcomes from patient medical records were collected. All de-identified data were abstracted into a secure online electronic data capture system. Data were aggregated by first and second hospitalizations. First hospitalization was defined as the single procedure for direct-to-implant IBR and first of two procedures for a two-stage IBR. Second hospitalization was defined as the second of two procedures for a two-stage IBR. Hospitalization does not imply an inpatient admittance to a hospital, as IBR procedures may have been conducted in the hospital-inpatient setting, hospital outpatient department, or an ambulatory surgical center.

Outcomes analyzed included self-reported pain severity on a scale of 0 to 10 (categorized for analysis as mild, 0–4; moderate, 5–6; severe, 7–10)[14]; HRU outcomes, which included hospital length of stay (LOS; ≤23 hours, ≥24 hours) and prescribed use of pain and muscle relaxant medications [intravenous [IV] narcotics, oral opioids, muscle relaxants, nonsteroidal antiinflammatory agents (NSAIDs), other]; and postprocedure complications occurring at hospitalization or within 12 months after IBR (surgical site infection, seroma, grade III/IV capsular contracture, dehiscence, flap necrosis, hematoma, malposition/asymmetry, muscle animation deformity, pain, expander/implant/ADM exposure, and unplanned explantation). Pain severity before and immediately after the procedure and before discharge, LOS, and medication use were assessed at the first hospitalization (all patients) and the second hospitalization (two-stage patients). HRU outcomes occurring around the time of the IBR procedure were reported.

Statistical Analysis

All analyses were conducted with the full analysis set, which consisted of all patients who met the inclusion and exclusion criteria. Ordinary least-squares regression models were used to calculate the least-squares mean difference, 95% confidence intervals (CIs), and *P* values for self-reported pain severity. Logistic regression models were used to calculate risk ratios, 95% CI, and *P* values for analysis of HRU items and each type of complication. All significance tests were two-sided, with a 5% significance level with no adjustments for multiplicity. All analyses were performed with SAS version 9.4 (SAS Institute, Cary, N.C.).

Initial feasibility assessments determined that a sample size of 456 patients (228 per group) was required to provide 80% power to detect a mean difference in LOS when the true difference is 13%. Although the planned sample size was not obtained during data collection, the observed difference in LOS is statistically significant.

To mitigate potential bias due to differences in patient or surgical characteristics and preserve sample size, inverse probability treatment weighting (IPTW) was used to create similar groups by controlling for prespecified confounding factors [age, body mass index category, race, ethnicity, duration of follow-up, diabetes, history of smoking, and IBR characteristics (pain severity before IBR, laterality, American Society of Anesthesiologists grade, staged approach, preoperative chemotherapy, postoperative chemotherapy, cancer stage, mastectomy type, prior lumpectomy)]. Each patient in the group was assigned a propensity score conditional on observed baseline covariates (ie, probability of receiving the DP or PP surgical technique). Weighting patients by the inverse of the propensity score creates a sample in which the type of IBR technique is independent of the measured baseline covariates.[15] IPTW allows for maintenance of sample size, as patients are not lost during matching. Counts after IPTW are the stabilized counts after weighting by IPTW. Consequently, the counts differ from the nonweighted counts and could include noninteger values. A standardized difference less than 20% indicates a small effect size and good balance between groups.[15,16] All further statistical analyses were conducted with data obtained after IPTW.

RESULTS

Patients

The observation period ranged from 3 to 12 months after the IBR (mean, 11.0 months), through February 28, 2019. Baseline characteristics of the patients are shown in Supplemental Digital Content 1. (**See table, Supplemental Digital Content 1,** which shows baseline demographic and clinical characteristics, **http://links.lww.com/PRSGO/C432**.) The majority of patient data came from two of the five surgical sites [190/261 patients (73%)]; generally, there was a balance between the number of patients undergoing DP and PP procedures at each of the sites. [**See table, Supplemental Digital Content 2**, which shows number of IBR patients per site (before IPTW), **http://links.lww.com/PRSGO/C433**.] Of the 261 eligible patients (DP = 122, PP = 139 [before IPTW adjustment]), 187 (72%) underwent a bilateral procedure, resulting in a total of 448 (DP = 211, PP = 237) breast records. Sixty-seven patients (DP = 20, PP = 47) underwent direct-to-implant reconstruction and 194 patients (DP = 102, PP = 92) underwent two-stage IBR. One surgical site performed pectoral blocks in all patients undergoing immediate IBR [n = 22; DP = 11, PP = 11 (before IPTW adjustment)]. Before IPTW adjustment, the types of implants were as follows: smooth (DP = 42/122, 34.4%; PP = 106/139, 76.3%), textured (DP = 44/122, 36.1%; PP = 14/139, 10.1%), and unknown (DP = 36/122, 29.5%; PP = 19/139, 13.7%). Among the breasts undergoing IBR, there were higher rates of stage I and II cancer at first hospitalization in the PP group (37.6%) compared with the DP group (30.3%). After IPTW adjustment, weighted counts consisted of 255 patients (DP = 130, PP = 125) representing 441 (DP = 226, PP = 215) breast records.

Characteristics were well balanced between the DP and PP groups, with standardized differences of less than 20% after IPTW. All statistical analyses were based on weighted counts after IPTW adjustment. (**See table, Supplemental Digital Content 1**, **http://links.lww.com/PRSGO/C432**.) (**See table, Supplemental Digital Content 2**, **http://links.lww.com/PRSGO/C433**.)

Pain Severity

At baseline, 93.5% of all patients reported mild pain, with no statistically significant difference between groups. Patients in the PP group reported statistically significantly less pain immediately after the procedure and before discharge compared with patients in the DP group at both the first (all patients) and second (two-stage patients) hospitalizations (Fig. 1). At the first hospitalization, mean (SD) pain severity scores with the PP versus DP techniques were 4.0 (2.35) versus 5.1 (2.60), respectively ($P = 0.0002$), immediately after the IBR procedure, and 2.2 (1.80) versus 3.2 (1.78), respectively ($P < 0.0001$), before discharge.

The proportions of patients reporting mild, moderate, and severe pain immediately after the procedure with the PP versus DP techniques and before discharge at first and second hospitalization are shown in Supplemental Digital Content 3. (**See table, Supplemental Digital Content 3,** which shows pain severity with DP versus PP immediately after IBR procedure, and before discharge, at first and second hospitalization, **http://links.lww.com/PRSGO/C434**.) Overall, patients in the PP group were 1.1 to 1.5 times more likely than patients in the DP group to report mild pain, instead of moderate or severe pain, related to the first hospitalization or second hospitalization. Moderate or severe pain immediately after the IBR procedure at first hospitalization was reported statistically significantly less frequently with the PP versus the DP technique (40.8% versus 59.8%, respectively; $P = 0.0020$). The difference in the frequency of reported moderate or severe pain between the PP and DP groups before discharge was not statistically significant (12.2% versus 19.9%, respectively; $P = 0.0814$). At the second hospitalization, moderate or severe pain immediately after the procedure was reported statistically significantly less frequently with the PP versus the DP technique (13.2% versus 43.6%, respectively; $P < 0.0001$). Before discharge, the proportion of patients with moderate or severe pain was reported statistically significantly less frequently with the PP versus the DP technique (1.2% versus 13.6%, respectively; $P = 0.0013$). (**See table, Supplemental Digital Content 3,** **http://links.lww.com/PRSGO/C434**.)

Healthcare Resource Utilization

There was a statistically significant difference between groups in patient LOS during the first hospitalization for IBR (Fig. 2), with a greater proportion of patients in the PP group having an LOS 23 hours or less compared with patients in the DP group [risk ratio (95% CI), 0.701 (0.547–0.900); $P = 0.0052$]. During the second hospitalization, there was no statistically significant difference in hospital LOS of 23 hours or less between groups [risk ratio (95% CI), 0.565 (0.087–3.671); $P = 0.5499$].

Use of IV narcotics, oral opioids, muscle relaxants, NSAIDs, and other medications during the IBR procedure stay is summarized in Table 1. No statistically significant differences in proportions of patients prescribed these medications were found between the DP and PP groups during the first hospitalization; however, a lower percentage of patients in the PP group were prescribed IV narcotics. During the second hospitalization, the PP group had statistically significantly lower IV narcotic use versus the DP group (37.5% versus 55.3%, respectively; $P = 0.0172$); use of the other medications was not statistically different between groups.

Complications

The overall rate of complications in both groups was low. During the IBR procedure stay, complications at the first hospitalization were reported for two of 215 (0.8%) breasts in the PP group and zero of 226 (0.0%) breasts in the DP group; complications at the second hospitalization

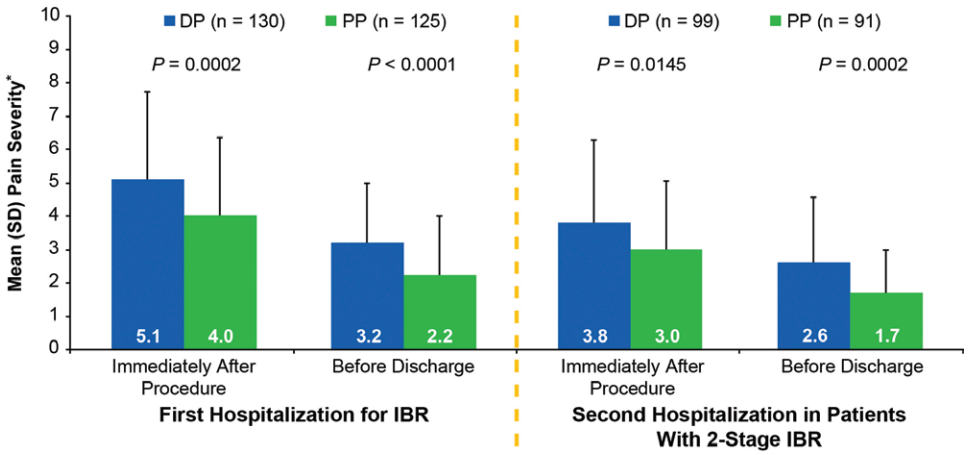

Fig. 1. Mean (SD) patient-rated pain severity at first and second hospitalization for IBR after adjustment using IPTW. *Pain was categorized on a scale of 0–10 (mild, 0–4; moderate, 5–6; severe, 7–10).

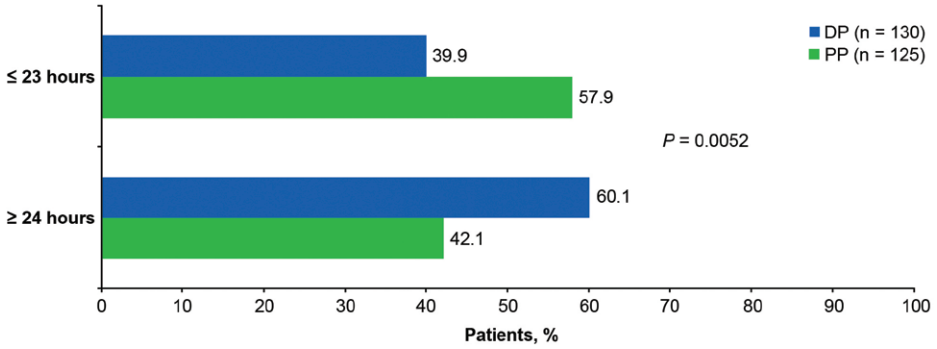

Fig. 2. Proportions of patients with LOS ≤ 23 hours and ≥ 24 hours at first hospitalization after adjustment using IPTW.

Table 1. Medication Use during IBR Procedure Stay

Medication, n (%)	DP*	PP*	Risk Ratio (95% CI)	*P*
First hospitalization for IBR†	n = 130	n = 125		
IV narcotic	90.8 (69.8)	76.2 (61.1)	0.876 (0.732–1.048)	0.1486
Oral opioid	115.2 (88.6)	112.5 (90.2)	1.019 (0.936–1.109)	0.6659
Muscle relaxant	51.9 (39.9)	57.0 (45.7)	1.146 (0.862–1.524)	0.3477
NSAID	14.1 (10.8)	23.1 (18.5)	1.714 (0.926–3.173)	0.0862
Other drugs	11.1 (8.5)	5.5 (4.4)	0.519 (0.193–1.398)	0.1945
Second hospitalization for IBR†	n = 99	n = 91		
IV narcotic	54.6 (55.3)	33.9 (37.5)	0.678 (0.492–0.934)	0.0172
Oral opioid	60.0 (60.8)	63.0 (69.6)	1.144 (0.929–1.410)	0.2062
Muscle relaxant	17.8 (18.1)	12.8 (14.2)	0.784 (0.406–1.515)	0.4689
NSAID	9.5 (9.6)	17.1 (18.9)	1.976 (0.942–4.145)	0.0717
Other drugs	0	1.3 (1.4)	NC	NC

CI, confidence interval; NC, not computable.
*The counts presented are the stabilized counts after IPTW.
†Percentages may add up to more than 100%, as patients may take more than one medication.

were reported for two of 163 (1.2%) breasts in the PP group and zero of 172 (0.0%) breasts in the DP group. After discharge, the total number of complications was 34 for the PP group and 33 for the DP group, with mean (SD) follow-up of 10.9 (2.0) and 10.8 (2.3) months, respectively (after IPTW adjustment). Corresponding rates of complications were 27 of 213 (12.5%) breasts in the PP group and 30 of 224 (13.6%) breasts in the DP group, and the difference was not statistically significant [risk ratio (95% CI), 0.916 (0.563–1.488); $P = 0.7225$]. Figure 3 shows the rates of individual complications in each group after discharge; none of the differences between groups was statistically significant.

DISCUSSION

The PP technique of IBR after mastectomy for breast cancer has been used increasingly more often in recent years and has the potential to change the surgical approach to IBR.[6,7,10,13] Concomitantly, the need for comparative data to inform surgeons on key outcomes has grown. This multicenter retrospective study compared clinical and HRU outcomes data from the medical records of 261 patients who underwent either a DP or PP procedure for IBR after mastectomy. The findings showed that use of the PP procedure was associated with statistically significantly less self-reported pain immediately after IBR and before discharge at the first and second (two-stage patients) hospitalizations, statistically significantly higher proportion of patients with an LOS of 23 hours or less during the first hospitalization, and statistically significantly less IV narcotic use during the second hospitalization. The reduced pain and shorter LOS associated with the PP procedure may reflect the shorter surgery time overall and the less involved surgery compared with the DP procedure, which includes pectoral muscle elevation. The rate of complications after discharge was very low with both procedures and not statistically significantly different between patients in the DP and PP groups. In aggregate, the findings suggest that there may be tangible benefits related to clinical outcomes and HRU with the PP technique in IBR.

Most studies comparing the DP and PP techniques in breast reconstruction are single-site retrospective studies with limitations in sample size (ranging from 26 to 110 patients in the PP groups and from 59 to 115 patients in the DP groups),[13,17–20] in contrast to the current multicenter study, which was carried out at five surgical centers throughout the United States with IPTW-weighting to balance the groups. Results are inconsistent across the prior studies, which may be a result of smaller sample sizes and inadequate power to detect differences, dissimilarities in

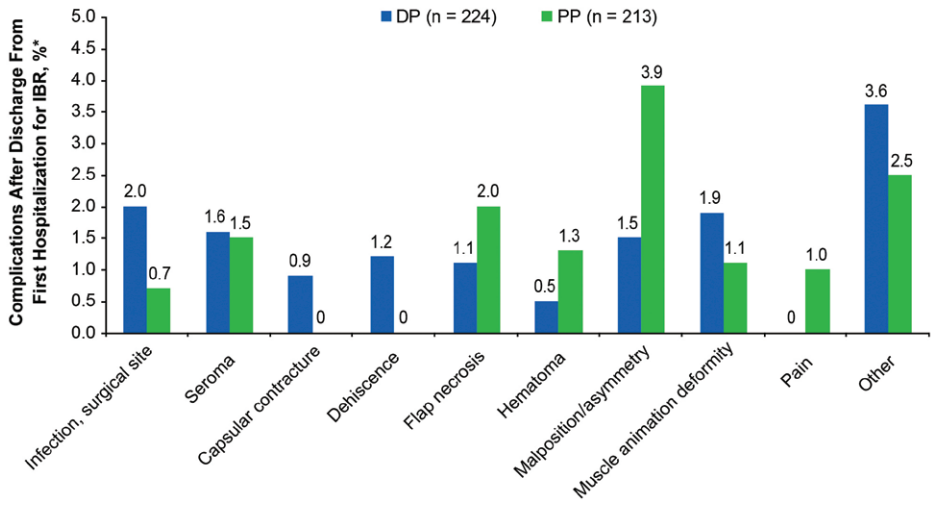

Fig. 3. Frequencies of complications after discharge from first hospitalization after adjustment using IPTW. Complications were analyzed with the breast as the unit of analysis. *Complications shown were present in at a least one group.

study design and analysis, and the sequelae of the learning curve associated with the PP technique. Nonetheless, there are points of consistency with findings from other studies and the current findings. Statistically significantly lower average pain scores during hospitalization, as assessed on the visual analogue scale, in PP [3.15 (1.57)] versus DP [4.05 (0.95)] patients were found in one retrospective study[19] and are similar to the first hospitalization pain scores in the current study. Another retrospective study found statistically significantly lower pain scores in PP versus DP patients 12 hours to 30 days after surgery.[20] A prospective study found statistically significantly lower pain intensity and analgesic consumption on postoperative days 1 and 7 among patients who underwent PP IBR compared with patients who underwent subpectoral IBR.[21] Although LOS was similar between procedures in the preceding study, the PP procedure had advantages compared with the DP procedure in terms of shorter time to return to work, medication costs, and rates of second operation to achieve symmetry.[21] In addition, the frequency of complications was largely similar in-between groups, in line with literature findings.[13,18,20] but with malposition/assymetry being more disparate.

The current study is unique in that it was a multicenter study representing both private and large institutional academic practices and broad geographic regions (East, Southeast, Midwest, South Central, and Pacific Northwest). Time periods of procedure overlapping at each center were excluded when selecting the PP and DP populations to mitigate any learning curve effect or confounding by indication in the comparisons between PP and DP, and consecutive sampling and the IPTW statistical technique were used to minimize bias and ensure balance between groups. In addition, the DP and PP populations analyzed were larger than other studies (DP, n = 130; PP, n = 125 after IPTW).

Although the current study was designed to encompass patients from throughout the geographic regions of the United States, it may not be representative of all patients undergoing IBR or of all practices in the United States in terms of levels of surgeon experience, standards of care, and characteristics of patients. Only one ADM was used in this study; results may differ compared with other ADMs used in DP and PP procedures. One surgical site used pectoral nerve blocks, which may have affected some study results (eg, pain severity immediately after IBR). As with any retrospective review of medical records, data collection is limited by available reported data, and surgical techniques may have varied between centers. Prospective studies using standardized surgical protocols would be needed to more fully address differences between DP and PP techniques. Further insight could also be gained by reporting on patient-reported outcomes, as well as details on outpatient management such as drain care and length of time with drains in place.

CONCLUSIONS

The results of this multicenter retrospective analysis comparing the DP and PP techniques in IBR lend support to the growing body of literature reporting the advantages of the PP technique in IBR. This study suggests the PP technique may have better outcomes for patients compared with the DP technique, as shown by less pain during hospitalization, less IV narcotic use, and shorter LOS. Larger studies including prospective studies with long-term follow-up are warranted to further elucidate these differences.

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