

SOCIETY FOR SAMBA AMBULATORY ANESTHESIA
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 ARIZONA BILTMORE • PHOENIX, AZ



Regional Blocks for Mastectomy with Immediate Expander Reconstruction: A Cluster-Randomized Trial of 1507 Patients


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***No disclosures**

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We conducted a large-scale (N = 1500), clinically integrated randomized trial at our ambulatory surgery center



Josie Robertson Surgery Center

- High volume of mastectomies
- Regional blocks are standard of care
- ERAS protocols
- Robust research infrastructure


We compared three different nerve block approaches for bilateral mastectomy with immediate implant-based reconstruction¹

1. Tokita et al. Clin Trials. Jun 19 2024;17(407):45241250087

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Reason #1: To better address acute pain after mastectomy



- Acute postoperative pain risk factor for chronic pain after breast surgery¹
- Optimal regional block for mastectomy with immediate expander reconstruction unclear
- Prior research focused on non-reconstructive breast surgeries²


Image: NY Times

1. Rogawsky et al. Eur J Cancer Care (Engl). Jul 2022;31(4):e13631
 2. Woodworth et al. Reg Anesth Pain Med. Sep/Oct 2017;42(5):509-531

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Reason #2: To show that a large, high-quality clinical trial is possible in the ambulatory surgery setting



Reasons why we need greater efficiency in clinical research in anesthesiology:

- We are a predominantly clinical specialty
- No time for research
- Large trials are \$\$\$
- Limited funding
- We rely on surgeons to generate trial subjects
- We do not meet patients in advance, how to consent patients for research?
- Need pragmatic trials conducted in "real world" settings

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Clinical question: Which block approach is most optimal for decreasing postop opioid use among patients undergoing mastectomy?

1. Paravertebral block (PVB)
2. Paravertebral block (PVB) + PECS-1
3. Serratus + PECS-1

Hypothesis: Combination blocks (2 or 3) are superior to PVB alone (1) in reducing **postoperative opioid consumption** (primary outcome)

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We utilized cluster randomization on a monthly basis

Power and sample size:

- Alpha 0.05, two-sided superiority test
- N=1500 (500 in each of the 3 arms)
- 86% power to detect a difference of 1/6th of a S.D. in **total postop opioids (primary outcome)** between the combined nerve block groups (arms 2 and 3) compared to PVB alone (arm 1)

Randomization "Block of the month" (Standard of care)

Informed Consent

January February March

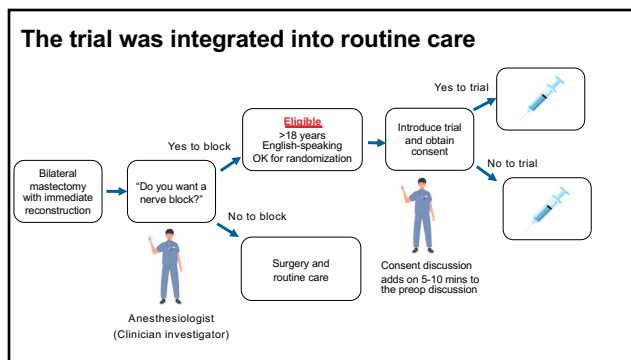
Arm 1: PVB (approx. n=500)

Arm 2: PVB + PECS-1 (approx. n=500)

Arm 3: Serratus + PECS-1 (approx. n=500)

Expected accrual time: 4 years
Actual accrual time: 3.7 years

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Results



- N = 1507 patients were randomized between 2019 and 2023
- PVB: 492; PVB + PECS-1: 446; serratus + PECS-1: 568
- >90% of eligible patients ended up on the trial
- Baseline demographics and co-morbidities were **extremely similar** among groups
 - (selection bias not observed in this study possibly due to very high accrual rate)
- 2% difference in top quartile of postop opioids between PVB and combined block groups which was small and not statistically significant
- No statistically significant differences for any secondary outcomes aside from total intraoperative opioid use (1.4 MME higher in the combined arm, $p=0.040$)
- One serious adverse event (pneumothorax; 0.07%) in the serratus + PECS-1 arm

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No evidence that combination blocks had an effect on any endpoints

Characteristic ¹	PVB N=492 ²	PVB+PECS-1 N=446 ²	Serratus+PECS-1 N=568 ²	Combined PECS N=1046 ²	Adjusted Difference	95% CI	p-value
Top Quartile Postoperative MMEs	129 (26%)	122 (27%)	125 (23%)	247 (24%)	-1.9%	-2.7%, 6.5%	0.4
Total Postoperative MMEs	23 (21)	22 (18)	20 (17)	21 (18)	2.1	0.07, 4.1	0.042
PONV Rescue	127 (26%)	100 (22%)	138 (24%)	238 (23%)	1.8%	-2.6%, 6.2%	0.4
Maximum PACU Pain 9-10	79 (16%)	57 (13%)	82 (14%)	139 (14%)	2.4%	-1.7%, 6.6%	0.2
Total Intraoperative Fentanyl (mcg)	133 (67)	131 (60)	144 (64)	138 (63)	-4.9	-12, 1.8	0.15
Total Intraoperative MMEs	27 (13)	27 (13)	29 (13)	28 (13)	-1.4	-2.8, -0.07	0.040
Ambulation Time (minutes)	530 (329)	528 (324)	526 (326)	531 (325)	-1.5	-43, 39	>0.9
Ambulation Distance (feet)	579 (496)	564 (545)	569 (455)	567 (498)	12	-51, 74	0.7
Discharge Time	12.1 (1.5)	12.1 (1.4)	12.0 (1.4)	12.0 (1.5)	0.09	-0.07, 0.25	0.3
Urgent Care Center Visit within 30 days	34 (6.9%)	39 (8.7%)	35 (6.2%)	74 (7.3%)	-0.39%	-3.3%, 2.5%	0.9
Transfer	6 (1.2%)	10 (2.2%)	4 (0.7%)	14 (1.4%)	-0.16%	-1.5%, 1.2%	>0.9
Readmission within 30 days	20 (4.1%)	24 (5.4%)	25 (4.4%)	49 (4.8%)	-0.77%	-3.1%, 1.6%	0.6

¹Missing data: Ambulation time 433, ambulation distance 403, discharge time 43
²PVB, paravertebral; PECS-1, pectoral nerve block; CI, confidence interval; MMEs, oral morphine milligram equivalents; PONV, postoperative nausea and vomiting; PACU, post-anesthesia care unit

Table 1. Outcomes and estimated differences along with their corresponding 95% confidence intervals for the average patient by randomization arm.

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Limitations



- Non-blinded
- No non-block arm
- No testing of block effect prior to OR
- Technique and dosing not standardized
- ?replicability at other institutions

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Conclusions

- Combined block approaches were comparable to paravertebral block alone
- Choice of block approach should be based on clinician experience and familiarity with block technique, patient factors, safety considerations
- Large, randomized trial using a clinically integrated design is feasible in the ASC, allows low-cost research in busy clinical settings



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