surgeries

MDPI

Supplementary Materials

Opioid Sparing at 24 h after Total Shoulder Arthroplasty by Undiluted Liposomal Bupivacaine Single Shot Interscalene Block: A Randomized Clinical Trial, First Results

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Determination of statistical sample was completed as per our approved protocol, which we are quoting verbatim: "The current postoperative Narcotics Usage during first 72 hours after PACU discharge in Milligrams Morphine Equivalents (MME) is approximately 32. We expect that usage to decrease by 30% which is approximately 22 MME. Accordingly, for the primary outcome of decrease in post-operative morphine usage, a total sample size of 46 (23 per group) achieve 91.250% power to reject the null hypothesis of equal means when the population mean difference is μ1 - μ2 = 32.0 - 22.0 = 10.0 with standard deviations of 10.0 for both groups and with a significance level (alpha) of 0.050 using a two-sided two-sample unequal-variance t-test. To consider possible dropouts we plan to enroll 50 patients."

All sixty patients were randomized with blinded envelopes. However, the procedure was not blinded because one group received a single interscalene injection while the other group had a continuous catheter insertion. After randomization, the envelope was opened, just before initiation of the block.

Due to subsequent concern by the IRB, that a single Exparel injection of 133 mg may be insufficient to provide sufficient postoperative analgesia, a special request was made from our ethics committee to evaluate the first ten randomized patients (5 in each respective group) to verify that pain levels in the first 72 hours never exceeded a value of 7 VAS (visual analog scale) score. Otherwise, the study would not have proceeded. We completed this task successfully and we were able to continue this study; at that point, we decided to collect data for sixty patients. The IRB approved the study expansion to sixty patients.

To verify our results, we also are submitting individual values for MME (Morphine Milligram Equivalent) for the first 24 hours for the two groups of 30 patients.

Table S1. Individual values for MME (Morphine Milligram Equivalent) for the first 24 hours for the two groups of 30 patients.

Exparel		**Ropivacaine**	
ID#	24 hours After discharge (MME)	ID#	24 hours After Discharge (MME)
1	22.5	2	85
3	5	4	10
6	35	5	25
7	0	8	45
10	20	9	30
11	20	14	40
12	25	15	20
13	20	16	25
17	0	19	50
18	15	20	20
22	60	21	40
23	68.5	24	47.5
27	25	25	15
28	20	26	37.5
29	45	30	30
32	20	31	221
34	30	33	20
35	15	36	60
39	13.5	37	92
40	90	38	20
41	25	42	5
43	35	45	25
44	10	46	30
47	30	49	45
48	15	50	40
51	15	55	30
52	20	56	15
53	20	58	56
54	5	59	25
57	20	60	30
Mean	**24.8**		**41.1**
SD	**19.2**		**39.3**

Note: "ID #" corresponds to the sequence from the blinded envelopes..