The ALOHA Trial: (Intra-Articular Local Anaesthetic in Hip Arthroscopy) – A Double-Blinded, 3-Arm Randomised Controlled Clinical Trial Comparing Pre-Emptive, High- and Low-Dose Intra-Articular Local Anaesthetic in Hip Arthroscopy

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Abstract

Background Pain after hip arthroscopy is variable but can be severe [11-point Numerical Rating Scale (NRS-11) pain scores of 10] despite multimodal analgesia. Although postoperative rescue regional analgesia is useful in these cases its efficacy may be limited by the maximum safe dose of local anaesthetic (LA) permissible when high-dose intra-articular local anaesthetic (IALA) has already been used. IALA may reduce acute postoperative pain after hip arthroscopy, however neither its optimum dose nor timing of administration have been systematically evaluated. **Methods** In 132 randomly assigned adult patients scheduled for therapeutic hip arthroscopy we compared the effects of two different doses of IALA given at procedure end (Group L [low-dose]: 100mg ropivacaine; Group H [high-dose]: 200mg ropivacaine). We also investigated the effect of an additional pre-emptive dose at the beginning of the procedure (Group P [pre-emptive]: 100mg ropivacaine at procedure start and end). **Results** There were no statistically significant differences between groups for NRS-11 pain scores in recovery (mean[SD]: Group L – 2.2[1.9]; Group H – 2.3[2.1]; Group P – 2.7[2.5]; lowest $p = 0.6$), or post recovery Visual Analogue Scale (VAS) pain scores [largest mean difference VAS 1.5 hours: 5mm ($p = 0.32$); VAS 2 hours: 5mm ($p = 0.35$); VAS 4 hours: 2mm ($p = 0.7$); VAS 6 hours: 3mm ($p = 0.7$)]. There were also no significant differences in antiemetic usage and requirement for rescue fascia iliaca block (FIB) between groups. **Conclusions** Compared to a single 100 mg dose of ropivacaine at the end of the procedure, we were unable to demonstrate any advantage of either a higher dose IALA or a pre-emptive dose IALA when multimodal analgesia is used. Lower-dose IALA could reduce total systemic LA absorption if a given rescue regional analgesic LA dose is used postoperatively.

Background

Acute pain at rest following hip arthroscopy varies greatly but can be severe (11-point Numerical Rating Scale [NRS] up to 10[1]) despite multimodal systemic analgesic therapy, requiring total intraoperative and recovery room IV morphine doses of up to 0.3mg/kg IV morphine[1]. Pre-emptive regional analgesic techniques offer superior analgesia but carry with them significant risks of falls[2], delayed mobilization[3] and neuropraxias[4]. Fascia iliaca blockade (FIB) has been shown to be a useful analgesic adjunct[5] but in our practice has only been used as a rescue analgesic in approximately 3-4% of cases[1]. The precise cause of severe early postoperative pain at rest after hip arthroscopy is unknown; use of high pressure intra-articular fluid infusion has been implicated[1], suggesting that the degree of peri-articular soft tissue swelling may be causative. It is a frequent clinical observation that after approximately 6 hours soft tissue swelling improves and coincides with rapid improvement in pain and mobility. This rapid improvement continues to the morning of postoperative day 1 when almost all patients are able to be discharged home on crutches with minimal oral analgesia.

Intra-articular local anaesthetic (IALA) for hip arthroscopy has been shown to be of analgesic benefit in some small studies[6, 7]. Local anaesthetic (LA) agents have been shown to confer pre-emptive analgesic

effects[8], however no comparative literature exists regarding the optimal dose and timing of IALA administration. If maximum recommended IALA doses are more efficacious than lower doses, side effects of systemic analgesics and the need for rescue regional analgesia may be reduced; conversely, if lower dose IALA is similarly efficacious, a given FIB rescue dose will be less likely to result in higher systemic LA absorption. Hence we hypothesized that the pre-emptive as well as postoperative administration of, and increased postoperative dosing of IALA, would have improved analgesic efficacy and postoperative opioid usage in patients undergoing therapeutic hip arthroscopy.

Methods

This study was approved by our institution's Human Research and Ethics committee (Melbourne Health HREC, approval # 2013.195) and registered under the Australian & New Zealand Clinical Trials Register (ACTRN #12614001121651). Approval was granted for protocol variation when increased sample size was necessary to avoid a Type 2 error in the outcome measures (#2013.195.P1-2). We conducted this study as per CONSORT recommendations. (See figure 1.) All patients provided written informed consent to be included in the trial. Inclusion criteria were age >18 years, and planned therapeutic hip arthroscopy for procedures on the ligamentum teres, labrum, or articular aspects of the femur or acetabulum. Patients were excluded if the arthroscopic procedure planned was for ilio-tibial band release alone, or if there were contraindications to any of the perioperative drugs in the study protocol. The primary study outcome measures were median recovery 11-point Numerical Rating Scale (NRS-11) assessments of pain, and Visual Analogue Scale (VAS) assessments of pain measured at 1.5, 2, 4 and 6 hours postoperatively at rest. Secondary outcome measures included highest and lowest recovery NRS-11 at rest, recovery analgesic and anti-emetic usage, total & 24 hour postoperative opioid analgesic and anti-emetic use, and repeated analysis of all pain outcomes corrected for pre-operative assessments of pain (ie. study VAS – pre-operative VAS = corrected VAS). Patients performed their preoperative VAS assessment at rest in the supine position whilst in the pre-anaesthesia bay. Recovery NRS-11 assessments were made 5-10 minutely depending on frequency of titrated IV morphine bolus requirements, until the patient's NRS-11 was <5 or until analgesia was defined as satisfactory by the patient, at which time they were discharged to the ward. Postoperative VAS time points for pain assessment and the 24 hour postoperative period were calculated from the time of application of surgical traction. Ward VAS assessments were performed by nursing staff, instructing patients to mark a single line across an uninterrupted horizontal scale where the extreme left- and right-hand extremes of the scale were marked as "No Pain" with smiling face schematic, and "Pain as Bad as it Possibly Could Be" with crying face schematic, respectively.

132 adult patients were recruited from a single surgeon's practice and randomly allocated to 1 of 3 groups: i) Low-dose LA (Group L - 100mg ropivacaine at end of procedure), ii) High-dose LA (Group H - 200mg ropivacaine at end of procedure) and iii) Pre-emptive LA (Group P - 100mg ropivacaine just prior to and at end of procedure). Random permuted block sizes of 9, 12 and 15 were used to achieve balanced group sizes whilst minimizing excessive runs of single group allocations. A web-based

randomization program (Sealed Envelope Ltd, London, UK) was used by a team member not involved with assessment of any patient outcome measures to allocate each patient's treatment group. After randomization subjects' IALA/ saline syringe orders were then allocated in a sealed envelope prior to the day of surgery. On the day of surgery the scrub scout nurse prepared IALA/ placebo syringes in the preparation room, separate from the operating room and out of sight from other team members, and did not share knowledge of syringe contents. Syringes were prepared under sterile conditions and as per the opened envelope instructions: Group L - pre-emptive syringe 20ml normal saline/ postoperative syringe 20ml 0.5% ropivacaine; Group H – pre-emptive syringe 20ml normal saline/ postoperative syringe 20ml 1% ropivacaine; Group P – pre-emptive syringe 20ml 0.5% ropivacaine/ postoperative syringe 20ml 0.5% ropivacaine. Pain assessments were performed by the recovery room nursing staff and postoperative ward staff, all of whom were blinded to the patients' group allocation.

Intraoperative anaesthesia and analgesia was standardized to spontaneous ventilation sevoflurane/ oxygen: air [50:50%] laryngeal mask anaesthesia, induction with 1-2mg/ kg IV propofol and 10-15mcg/ kg IV alfentanil, and administration of 1mg/ kg IV tramadol, 0.05mcg/ kg IV morphine, 40mg IV parecoxib and 1g IV paracetamol from the start of the procedure. All patients received 8mg dexamethasone and 1mg granisetron IV as preventative anti-emesis. Hip arthroscopy was performed in the lateral decubitus position and surgical traction was applied with a McCarthy Hip Distractor (Innomed, Inc, Savannah, GA, USA). Intra-articular access was facilitated with an arthroscopic infusion of Ringer's Lactate at constant pressures of 40mmHg. Ligamentum Teres tears were debrided, and synovitis treated with synovectomy, with the aid of a radiofrequency ablation probe (Vulcan Eflex Ablator Probe, Smith & Nephew, Andover, MA, USA). Labral tears were treated with circumferential suture anchor refixation (Nanotack Flex, Stryker, Sunnyvale, CA USA).

Pre-emptive LA was administered as soon as the initial arthroscopy portal was inserted into the hip joint, whilst LA administered at the end of the procedure was given via the arthroscopic portal just before portal removal. The study recovery protocol for postoperative analgesia offered subjects 1) IV morphine 1mg (if NRS-11 <7) to 2mg (if NRS-11 7 or above) 5-10 minutely, titrated up to 0.2 mg/kg for clinical review or until dose limiting side effects such as sedation or nausea and vomiting occurred, simultaneously with 2) IV tramadol 50mg 15 minutely, up to a total theatre and recovery room dose not exceeding 200mg. Breakthrough antiemetics offered were cyclizine 50mg IV (1 dose) and droperidol 10mcg/ kg (1 dose).

Patients were offered rescue FIB if recovery NRS-11 pain assessments were >5 despite maximum study protocol systemic analgesia, or if sedation, nausea or vomiting became rate-limiting factors to further administration of IV morphine. FIB was performed as originally described by Dalens[9] with 20ml of 0.5% ropivacaine. Patients with an NRS persisting above 5 or who were still dissatisfied with their analgesia at

this point were offered IV morphine via a Patient Controlled Analgesia device (PCA) and ketamine infusion of 0.1-0.2mg/ kg/ hr, and were included in the intention-to-treat analysis. Once discharged to the ward patients were initially offered 2.5-5mg oral oxycodone as first-line analgesia, 50-100mg oral tramadol as second-line analgesia, and 2.5-5mg intramuscular or subcutaneous morphine as third-line analgesia every 6 hours. 1mg IV bd granisetron and 50mg IV tds cyclizine were offered as needed for nausea and vomiting. Opioid doses were expressed as IV morphine equivalents; for tramadol we used the manufacturer's recommended equipotency of 1mg IV morphine = 10mg IV tramadol; for oxycodone, 2 mg oral oxycodone = 1mg IV morphine[10].

Statistical Analysis

All calculations were performed using GraphPad Prism 5 (GraphPad Software, CA, USA) and G*Power 3.1 (University of Dusseldorf, Dusseldorf, Germany) statistical software. As the difference between median and mean of each dataset was <25% of the lower value and sample sizes >30 we used parametric analyses. Categorical data were compared with chi-squared testing, and continuous data analysed with one-way ANOVA and Bonferroni multiple comparisons testing, with Bonferroni correction of p-values. (Recovery NRS-11: highest, median and lowest NRS-11 values; Postoperative VAS: mean values at 1.5, 2, 4 and 6 hours) between multiple pairs of groups. Patients lost to follow up with missing VAS data had all other trial data included in the final analysis; missing data was not imputed.

Power calculation

Sample size was determined "a-priori" with the use of G*Power V 3.1 (University of Dusseldorf, Dusseldorf, Germany). Morgenthaler et al found an overall reduction in VAS at rest after hip arthroscopy of [mean (SD)] of 10mm (18mm) over a 20-hr postoperative period when comparing the effect of IA Bupivacaine 50mg against placebo. Assuming approximate LA potency of 1mg Bupivacaine = 1.5-2mg Ropivacaine, and a linear dose-response of relationship between LA dose and reduction in postoperative VAS, each 100mg of IALA Ropivacaine reduces postoperative VAS by [mean (SD)] 10mm(18mm). With desired power of 0.8 the number of patients per arm required to demonstrate a mean VAS difference of 10mm by 2-tailed unpaired t-test at alpha of 0.05 was 17 patients. We chose to consider a 10mm VAS difference as significant because the use of multimodal analgesia would most likely reduce measured differences in the outcomes. Sample sizes were more than doubled in our study to account for multiple comparisons. The low frequency of need for rescue FIB in this population would require large sample sizes to detect differences between groups and hence we did not power this study for that purpose.

Results

Consistent with our study protocol of strict intention-to-treat analysis, all patients with missing postoperative pain score data had other retained data included in the final analysis. There were no acute complications from the use of IALA or rescue FIB. All patients were discharged home on the morning of postoperative day 1 with the use of crutches and oral analgesia. Figure 1 shows the CONSORT study summary; Table 1, patient demographics; and Table 2, the hip arthroscopic findings and interventions performed on each patient.

A total of 10 patients were partially lost to follow up with missing VAS assessments over the 1.5 – 6 hour postoperative study period (See Figure 1); 1 at all ward VAS time points; 4 at 2 hours; 4 at 4 hours; and 1 at 6 hours. Overall, patients' mean pain assessments appeared to be that of satisfactorily controlled pain; however recovery NRS-11 and postoperative VAS pain assessment ratings were highly variable (Tables 3 & 4).

Pain assessments appeared to be of greatest magnitude in the recovery room and at the ward at 1.5 hours postoperatively [mean (SD) Recovery NRS-11 highest pain score 3.5 (3.0); Postoperative VAS 1.5 hrs 36mm (18 mm). Postoperative mean VAS approximately halved at the 6 hour postoperative time point. Figure 2 shows the highest, lowest and median recovery NRS-11; Figure 3, 1.5 – 6 hour postoperative VAS. There was no statistically significant differences found between groups in pain assessments at any postoperative time points (See Tables 3 & 4). Correcting recovery NRS-11 and postoperative VAS for pre-operative VAS at rest did not change statistical significance except for the Lowest Recovery NRS-11 [$p=0.03$ between Group P (NRS-11 = 1.6) and Group L (NRS-11 = 0.7)]. Otherwise the largest difference between pain assessments was VAS 5mm at the 1.5 and 2 hours postoperative time points.

4% of patients received rescue FIB. Of the 6 patients receiving rescue FIB, all except 1 patient reported much improved pain; this patient was then prescribed a 0.15mg/ kg/hr ketamine infusion.

Overall intraoperative & recovery IV morphine equivalent analgesic doses were large [mean: SD (0.23: 0.1 mg/ kg), with doses in the remainder of the 24 hour postoperative period much smaller (0.09: 0.1 mg/ kg). There were no significant differences between groups in IV morphine equivalent analgesic doses (Group L = 0.22 mg/ kg; Group H = 0.23 mg/ kg; Group P = 0.24 mg/ kg). There were no significant differences in antiemetic doses between groups [largest difference between means in granisetron

requirements 0.07mg ($p = 0.6$); largest difference between means in cyclizine requirements 0.9mg ($p = 0.9$)]. Figure 4 shows postoperative analgesic doses.

Discussion

We present findings from a double-blinded, 3-arm randomized controlled trial of 132 patients comparing the analgesic efficacy of 1) high dose IALA at operation end, 2) low dose IALA at operation end, and 3) IALA both pre-emptively and at operation end. With the exception of lowest recovery NRS-11 pain scores, the results of our primary and secondary outcome measures showed no statistically or clinically significant difference between IALA groups in recovery or postoperative pain score outcomes, morphine equivalent analgesic requirements, or antiemetic requirements. Our study was not powered to detect a significant difference in requirement for rescue FIB.

We believe the finding of a statistically significant difference in the preoperative NRS-11 corrected recovery lowest pain scores by one-way ANOVA and by bonferroni multiple comparisons testing between groups L and P to be spurious, as the variability in the low scores at this time point was artificially reduced by limiting the lowest possible corrected NRS-11 to zero. The mean NRS-11 difference here of 0.9 is also unlikely to be of clinical significance as the NRS-11 scores (Group P: 1.6 and Group L: 0.7) are both very low, correlating with established definitions of mild pain[11].

Whilst the use of IALA doses compared with placebo has shown promise in improving analgesia after hip arthroscopy, we specifically designed our study to compare variable dosing and timing of IALA. Baker et al found that 25mg postoperative IA bupivacaine had opioid sparing effects compared with the same dose infiltrated around portal insertion sites[7], and Morgenthaler et al used 50mg postoperative IA bupivacaine vs IA placebo to achieve a mean 20-hour VAS superiority of 10mm at rest[6]. In knee arthroscopy, Tuncer et al[12] demonstrated superior analgesia up to 6 hours postoperatively when pre-emptive administration of 50mg IA bupivacaine was used prior to surgery, when compared with postoperative dosing. Goodwin demonstrated variable short-term pre-emptive effects[13, 14], whilst Fagan et al's study did not demonstrate superiority[15].

Several factors may account for the lack of any demonstrable effect with higher dose and pre-emptive administration of IALA in our study. Overall mean pain assessment scores were moderate-to-low, hence the perioperative use of good multimodal analgesia may have masked any benefit in IALA dosing or timing. Although we did not include a placebo arm in our study, we cannot exclude the possibility that any dose of IALA may lack significant efficacy when used in conjunction with systemic multimodal analgesia. Compared to our previous study[1] all patients received an arthroscopic fluid infusion pressure of

40mmhg rather than the more commonly used 80mmhg, and fewer patients received femoral osteoectomy; factors known to predispose to postoperative pain. Overall opioid requirements were similar in both studies, however, and are approximately equivalent to the requirements observed in other hip arthroscopic studies[16]. We did not assess VAS on weight-bearing or movement of the hip joint postoperatively; the greater pain experienced under these circumstances may have demonstrated a pre-emptive or dose-dependent IALA effect. Morgenthaler's positive study findings included a larger effect size when assessment of pain on movement was used, however his team also demonstrated a statistically significant effect on pain at rest. IALA may have an effect on intra-articular sources of pain (eg. osteoectomy sites; labral repairs and their bony anchors) however will be unlikely to affect pain related to extra-articular causes (eg. peri-articular soft tissue distension from extravasated arthroscopic infusion fluid). Peri-articular LA infiltration appeared to be effective for postoperative pain in hip arthroscopy in one retrospective study[17].

The potential for arthroscopic fluid to have washed out the IALA before it has had the opportunity to block neural sodium channels is possible. This has not influenced the effect of postoperative hip arthroscopic IALA in previous studies but could have affected our pre-emptive dose; effective pre-operative IALA used in some knee arthroscopic studies was given 20-30 minutes prior to portal insertion and irrigation[12].

Although our sample size was larger than most previous studies on IALA, the possibility of a type 2 error still exists. The further increase in statistical power afforded by our higher sample size however, adds strength to the existing literature that under a variety of surgical, patient and concomitant multimodal analgesic contexts, the analgesic effect of IALA is unlikely to be clinically significant. This increase in statistical power was achieved by intentionally reducing the VAS difference initially sought. This VAS difference may be considered clinically insignificant, but permits a larger sample size calculation for our study. Our power calculation was defined by VAS improvements at rest on a dose-to-VAS mm effect, however the comparator patient population in the study from where this data was obtained were all fishermen[6], who may have had a higher proportion of severe underlying osteoarthritis or need for femoral osteoectomy. This may have relatively amplified the efficacy of IALA in this study. As our study lacks a placebo arm, no comparative inferences can be made from our results regarding the effect of any local anaesthetic regime against no local anaesthetic at all when administered simultaneously with multimodal systemic analgesia. Our use of NRS-11 in the recovery room and VAS in the postoperative ward environment limits absolute comparisons between the pain assessments in the two scenarios. Whilst the two correlate, there is not complete concordance between these measures of pain severity.

Conclusions

Use of 100mg vs 200mg IALA at operation end, or 100mg pre-emptively and at operation end, appears to have no differing effects on acute pain, analgesic requirements, or antiemetic requirements after hip arthroscopy. Pain after therapeutic hip arthroscopy is highest in the recovery room and first 1.5 hours postoperatively, improving significantly by 6 hours postoperatively, and can be well managed with multimodal analgesia and appropriately titrated opioid administration. Rescue fascia iliaca blockade may be required in a small proportion of patients. As lower doses of IA ropivacaine do not appear to offer inferior analgesia in this context, we recommend that if IALA is to be used at all, use of 100mg IA ropivacaine will result in a lower total dose of LA administered to patients if rescue FIB of a given dose is required.

Abbreviations

Abbreviation	Definition
ALPHA	Intra-Articular Local anaesthetic in Hip Arthroscopy
NRS-11	11-point Numerical Rating Score for pain
LA	Local anaesthetic
IALA	Intra articular local anaesthetic
SD	Standard deviation
p =	P-value
VAS	Visual Analogue Scale for pain
FIB	Fascia Iliaca Block
ACTRN	Australian & New Zealand Clinical Trials Register
HREC	Human Research & Ethics Committee
CONSORT	Consolidated Standards of Reporting Trials
IV	intravenous
mg	milligram
mcg	microgram
PCA	Patient controlled analgesia
bd	Twice daily
tds	Three times daily
ANOVA	Analysis of variance
mm	millimetres
#	number
%	percent
ASA	American Society of Anaesthesiologists score
mins	minutes
Kg	kilogram
Hr	hour

Declarations

- **Ethics approval and consent to participate**

This study was approved by our institution's Human Research and Ethics committee (Melbourne Health HREC, approval # 2013.195). Approval was granted for protocol variation when increased sample size was necessary to avoid a Type 2 error in the outcome measures (#2013.195.P1-2). All patients provided written informed consent to be included in the trial.

- **Consent for publication**

Not Applicable

- **Availability of data and material**

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request. Restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of Bellbird Private Hospital administration

- **Competing interests**

The authors declare that they have no competing interests.

- **Funding**

No external funding was sourced for the design of the study; the collection, analysis, and interpretation of data; and in the writing of the manuscript.

- **Authors' contributions**

CT made substantial contributions to the conception and design of the study, the acquisition of data, and the analysis/ interpretation of data. He also drafted and revised the manuscript, and approved the final version for publication.

PT made substantial contributions to the conception and design of the study, the acquisition of data, and the analysis/ interpretation of data. He also drafted and revised the manuscript, and approved the final version for publication.

YMC made substantial contributions to the conception of the study, revised the manuscript for publication, and approved the final version for publication.

WH made substantial contributions to the conception and design of the stud. He also drafted and revised the manuscript, and approved the final version for publication.

LW made substantial contributions to the conception and design of the study and the analysis/ interpretation of data. He also drafted and revised the manuscript, and approved the final version for publication.

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Tables

TABLE 1 – PATIENT DEMOGRAPHICS, SURGICAL DURATION & NEED FOR RESCUE REGIONAL ANALGESIA

	Group L	Group H	Group P
Age (mean: SD)	40 (12)	38 (11)	38 (11)
Male (#:%)	54 (37%)	84 (58%)	86 (60%)
Weight (Kg: mean [SD])	78 (16)	77 (15)	78 (20)
# ASA 3 ^a	2	3	5
Surgical Duration [mins(mean:SD)]	30 (17)	31 (16)	28 (15)
Rescue FIB required (# patients) ^b	3	1	2

a: all remaining patients were ASA 1 and 2.

b: FIB = fascia iliaca block

TABLE 2 – ARTHROSCOPIC FINDINGS & SURGICAL INTERVENTIONS PERFORMED

	Group L (n = 44)	Group H (n = 44)	Group P (n = 44)
Femoral Osteoectomy	10	15	11
Acetabular Osteoectomy	4	12	7
Labral repair	24	34	34
Rim Chondroplasty	23	30	32
Microfracture	2	0	3
Ligamentum Teres debridement	35	38	38
Capsular Repair	1	1	0
Acetabular Chondral Damage	28	34	36
Extra-articular Approach	2	2	0
Intra-Articular Steroid Used	14	5	6

TABLE 3 - RECOVERY 11-POINT NUMERICAL RATING SCALE ASSESSMENTS OF PAIN

		Group L ^a		Group H		Group P
Highest NRS-11^b	Mean	2.9		3.1		3.5
	SD ^c	2.5		2.8		3.0
	One-Way ANOVA	p = 0.11				
	Bonferroni Multiple Comparisons corrected p	vs. Group H	0.37	vs. Group P	1.0 vs. Group L	0.13
Lowest NRS-11	Mean	1.4		1.6		2.2
	SD	1.5		1.9		2.1
	One-Way ANOVA	<i>p = 0.03</i>				
	Bonferroni Multiple Comparisons corrected p- values	vs. Group H	1.0	vs. Group P	0.16 vs. Group L	<i>*0.03</i>
Median NRS-11	Mean	2.2		2.3		2.7
	SD	1.9		2.1		2.5
	One-Way ANOVA	p = 0.09				
	Bonferroni Multiple Comparisons corrected p- values	vs. Group H	0.54	vs. Group P	1.0 vs. Group L	0.09

a: Group L = Low dose ropivacaine group, 100mg IALA at operation end; Group H = High dose ropivacaine group, 200mg IALA at operation end; Group P= Pre-emptive ropivacaine group, 100mg ropivacaine prior to operation start and at operation end.

b: 11-point pain Numerical Rating Scale

c: Standard deviation

TABLE 4 - POSTOPERATIVE 11-POINT NUMERICAL RATING SCALE ASSESSMENTS OF PAIN

		Group L ^a		Group H		Group P
VAS ^b 1.5 hrs (mm)	Mean	33		31		36
	SD ^c	18		16		19
	One-Way ANOVA	p = 0.33				
	Bonferroni Multiple Comparisons corrected p	vs. Group H	1.0	vs. Group P	0.93	vs. Group L
VAS 2 hrs (mm)	Mean	29		26		31
	SD	14		17		17
	One-Way ANOVA	p = 0.59				
	Bonferroni Multiple Comparisons corrected p	vs. Group H	1.0	vs. Group P	1.0	vs. Group L
VAS 4 hrs (mm)	Mean	20		20		22
	SD	14		13		18
	One-Way ANOVA	p = 0.28				
	Bonferroni Multiple Comparisons corrected p-values	vs. Group H	0.37	vs. Group P	1.0	vs. Group L

a: Group L = Low dose ropivacaine group, 100mg IALA at operation end; Group H = High dose ropivacaine group, 200mg IALA at operation end; Group P= Pre-emptive ropivacaine group, 100mg ropivacaine prior to operation start and at operation end.

b: Visual Analogue Scale

c: Standard deviation

Figures

Figure 1

ALOHA CONSORT DIAGRAM

Figure 2

RECOVERY NRS-11 PAIN SCORES

Figure 3

POSTOPERATIVE VAS PAIN SCORES

Figure 4

24 HOUR POSTOPERATIVE IV MORPHINE EQUIVALENT REQUIREMENTS