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Regional versus General Anaesthesia: Effect of Anaesthetic Techniques on Clinical Outcome in Lumbar Spine Surgery: A Prospective Randomized Controlled Trial

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Conflict of Interest

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Background

There are only a few prospective clinical trials to determine the effects of different anaesthetic techniques on clinical outcomes in lumbar spine surgery.-The purpose of this study was to evaluate differences between general anaesthesia (GA) and regional aesthesia (RA) in clinical outcome measures.

Methods

This was a single-centre, two-arm, randomised trial, which recruited patients undergoing lumbar spine surgery. The primary endpoint was morphine consumption (MC) during the first postoperative 48 hours. Apart from pain scores, patient self-questionnaires up to 6 weeks after surgery were conducted.

Results

One hundred patients were randomized into two groups of 50 patients, receiving either GA or RA. For the primary endpoint of cumulative MC at 48 h post surgery, no difference was found between GA and RA groups.

Anaesthesia time and transition time were significantly shorter ($p < 0.001$) in the RA group compared with the GA group. There was a significantly higher percentage of patient satisfaction in the RA arm vs the GA arm ($p < 0.001$). A significant difference for visual analogue scale (VAS) for pain was observed in the gender analysis over time: females had a higher VAS from the preoperative stage up to 6 weeks after the operation ($p < 0.001$).

Conclusion

There was no statistically significant postoperative difference in MC between GA and RA. RA led to significantly shorter anaesthesia and transition time and higher patient satisfaction. The VAS for pain score was significantly higher in the GA group at PACU start as in the RA group RA.

Introduction

Lumbar spine surgery can be performed using different anaesthetic techniques, such as general endotracheal anaesthesia (GA) or spinal-based regional anaesthesia (RA). Although RA is well established in other fields of orthopaedic surgery, GA is still the most commonly used method for lumbar surgery. This is due to the fact that often neurosurgeons and anaesthetists prefer GA even though on different reasons. Each anaesthetic method is associated with a side effect profile that affects the perioperative process in different ways (opioids: nausea, vomiting, pruritus, sedation; local anaesthetics: motor weakness). However, there is insufficient evidence to support differences in risk of major postoperative morbidity or mortality.

In a recent review, several studies were discussed that showed lower postoperative pain score for RA than for GA (1). Unfortunately, randomized control trials (RCTs) with a sufficient sample size to compare the two-techniques have provided conflicting results (2-5).

Data on surgery time, anaesthesia time, length of stay in the postoperative anaesthetic care unit (PACU), and postoperative analgesic dose requirements, were inconsistent among studies (6, 7, 9).

Despite a lack of conclusive data, there have been some indications that RA has lower postoperative morbidity and mortality compared with GA (10, 11). Furthermore, there are reports supporting the cost benefits of RA over GA (12, 13). This is mainly based on the significantly reduced anaesthesia time of spinal anaesthesia compared with GA in a retrospective evaluation of 473 lumbar surgeries (12).

The correlation between RA and specific outcome parameters is complex and until now, there has been no clear evidence for a strong recommendation to support the use of one technique over the other, either way (14). To help address this shortcoming, our goal was to gain a better understanding of the relationship between level of pain and type of anaesthesia. The main aim of this study was to identify changes in morphine consumption in a study containing sufficient numbers of patients in the two randomized groups undergoing RA or GA.

In the present study, we performed a prospective assessment of morphine consumption and used a visual analogue scale (VAS) to document indicators of level of pain and discomfort changes in symptom severity over time. In addition, the anaesthesia time, surgery time, transition time (defined as time from end of surgery to the start of the PACU stay), the severity of postoperative nausea and vomiting (PONV), in combination with levels of patient and surgeon satisfaction, were analysed.

Methods

Patients and design

This was a single-centre, two-arm, randomised-controlled superiority trial, which recruited patients undergoing elective, lumbar spine surgery. The study was conducted at the St. Anna Hospital in Lucerne, Switzerland, between January 2016 and August 2017. Eligible patients were randomized to one of two study arms, in which they received either a regional or general anaesthetic during surgery. The study was conducted in accordance with the Declaration of Helsinki and ICH Good Clinical Practices Guidelines. An independent ethics committee for our institution approved the clinical protocol and informed consent documentation (EKNZ Nr. 2015-261). All patients provided written informed consent. The protocol number of the study is CTU 0524 (University of Berne / Switzerland). The clinical trial is also registered with ClinicalTrials.gov (NCT03300089).

Adult patients scheduled to undergo elective lumbar spine surgery due to single- or multi-level herniated disc or spinal stenosis were eligible. Surgeries were performed by a senior neurosurgeon due to intractable pain despite conservative therapy or due to motor weakness. Exclusion criteria included American Society of Anesthesiologists (ASA) score ≥ 4, infection at the site of the operation field, long-term history ($\geq$ 6 months) of neuropathic pain at the operation site, revision surgery and/or follow-up lumbar spine operations, severe coagulopathy (platelet count < 100,000/mL^3 or thromboplastin time < 50%), allergy to local anaesthetics or opioids, previous drug dependency or chronic use of opioids ($\geq$ 6 months) and psychiatric disorders precluding capacity to provide informed consent.

Baseline variables included gender, age (years), ASA score (I-III), body mass index (BMI) at inclusion [kg/m^2], and primary diagnosis (herniated lumbar disc or spinal stenosis). VAS score for pain at rest was assessed at defined time points (from the preoperative stage up to 6 weeks after surgery) at the operation field and outside the operation field. The self-reported Euro Quality of Life (EQL-5D) questionnaire was completed by patients at the preoperative stage, at discharge and then 6 weeks later at the follow-up postoperative evaluation.

Randomisation

Patients were randomized electronically in a 1:1 ratio to one of the two trial arms (Figure 1). The allocation sequence was generated by an independent statistician at CTU Berne (University of Berne), who was not involved in the final analysis of the trial. The allocation

sequence was based on computer generated random numbers in randomly varying blocks of 2, 4, and 6 using the statistical software package Stata (StataCorp LP, College Station, TX, USA). Random allocation was stratified according to whether patients presented with spinal stenosis or herniated lumbar disc (two groups) and VAS score for pain at baseline (two groups; VAS < 5 and VAS ≥ 5).

Blinding

It was not possible to blind the surgeon or other staff members in the operation theatre, regarding type of anaesthesia, due to the obvious difference between GA and RA. However, in the follow-up phase 6 weeks after the operation, the surgeon was blinded to type of anaesthesia during the assessment of the functional and clinical outcome. The trial statistician was blinded to study allocations at the time of writing the statistical analysis plan (SAP), during data preparation and data validation as well as during the primary analysis of the primary and secondary outcomes. The trial statistician was subsequently unblinded when secondary and further sensitivity analyses were performed.

Clinical performance

In the GA group, patients were anaesthetized with fentanyl 4–6 μg/kg intravenously (iv). Initially, propofol was administered at a plasma target concentration of 6 μg/mL with a target controlled infusion (TCI) pump (Schnider model). All patients underwent endotracheal intubation through a bolus of atracurium 0.5 mg/kg iv. Maintenance of GA was achieved by a TCI of propofol with a bispectral index (BIS) target area of 40–50% and a remifentanil TCI pump (Minto model) with a plasma concentration of 2–4 ng/mL.

In the RA group, 15–20 mg of hyperbaric bupivacaine 0.5% (using single injection technique) plus 25 μg fentanyl spinal was given. The L3-L4 level was used preferentially for spinal anaesthesia; the selected level was shifted to L2-L3 or to L4-L5 based on the level to be operated. Surgery was initiated after checking for loss of sensation to cold. During surgery, patients were mildly sedated via a continuous iv infusion of propofol (TCI pump) or via an intermittent iv bolus of midazolam.

All patients were discharged from the operating theatre directly to the PACU. All procedures were performed by the same neurosurgeon. PACU discharge criteria included a VAS score for pain below 4, nausea under control and a sensoric block below the twelfth thoracic dermatome.

Clinical outcomes

The primary endpoint was cumulative morphine consumption (MC) at 48 h after surgery, recorded by an intravenous patient-controlled analgesia (PCA) pump.

The most important secondary endpoint was pain intensity. Pain intensity was always measured at rest with a VAS (0 = no pain, 10 = intolerable pain). VAS measurements were taken preoperatively, postoperatively upon arrival at the PACU, at the end of stay in the PACU, on the first and second postoperative day, at time of discharge, and finally at 6 weeks after the operation.

Additional secondary endpoints included anaesthesia time, the surgery time, length of stay in the PACU, the incidence and severity of PONV (0 = no PONV, 4 = severe PONV) (assessed upon arrival~~,~~ and departure from the PACU, and at 24 and 48 h after surgery), the urinary catheter rate in the PACU, patient satisfaction at discharge (0 = no satisfaction, 4 = complete satisfaction), and the surgeon's level of satisfaction with the anaesthesia (0 = no satisfaction, 4 = complete satisfaction). Patients'perception of their quality of life was assessed with the self-reported EQL-5D questionnaire (0 = no problem, 2 = extreme problem) at the preoperative stage, at discharge, and at 6 weeks after surgery.

Adverse events (AEs) or complications were monitored throughout the entire study for up to 3 months after the 6-week-follow-up period.

Statistical analysis

In the primary analysis, all patients were included in analysed in the full analysis set (FAS), according to the intention-to-treat principle. Additional secondary analysis on the per-protocol set was unnecessary, because this was identical to the FAS as (no violation of the protocol occurred). Statistical significance~~-~~for superiority was set at a two-sided α level of 0.05. All statistical analysis was performed by a statistician at CTU Bern, using Stata 14. The minimum sample size was calculated to enable detection of a difference in MC between treatment groups of 0.6 standard deviations, assuming normally distributed data. We calculated that a sample size of 45 patients per trial arm would provide 80% power to detect this difference with a two-sided p-value set at 0.05 (Student's t-test) and included 50 patients per treatment arm to account for a drop-out rate of 10 %.

Baseline, procedural and postoperative data for each treatment group were summarised as mean ± standard deviation (SD), median (25–75 percentiles), or as counts (%), p-values were calculated using chi-squared tests for categorical data or Wilcoxon rank tests for continuous data.

Differences in MC (the primary endpoint assessed postoperatively at 2 days) between treatment groups were assessed by linear regression, adjusted for the stratification factors used at the time of randomisation (e.g. type of operation and baseline VAS < 5 vs VAS ≥ 5). Robust standard errors were used to relax the assumption of identically distributed errors, and the distribution of the residuals of the linear model was inspected ~~in~~ using a quantile-quantile plot. The difference in the medians between the two groups was analysed and adjusted for the stratification factors, as described above. This model retained the assumption of independent errors but relaxed the assumption of normal and identically distributed errors.

Secondary endpoints compared longitudinal progression of postoperative VAS for pain between treatment groups. These assessments were performed using a linear mixed model (adjusted for the baseline VAS value at rest and the stratification factor diagnosis [spinal stenosis vs herniated lumbar disc]). Fixed effects were introduced for the intervention group, time points (categorical) and interaction terms between time points and groups, as well as a random intercept for patients. Differences between the two intervention groups at pre-specified time points (48 h postoperative, at discharge, 6 weeks postoperative) were calculated from this model and shown with a 95% confidence interval. Moreover, the averaged difference of the three postoperative time points (the day of operation, 24 h postoperative and 48 h postoperative) was determined.

For other continuous secondary outcomes (anaesthesia time, length of PACU stay, patient satisfaction, surgeon satisfaction, and EQL-5D), the same approach was followed as for the primary outcome. EQL-5D was-adjusted for the baseline value.

In a sensitivity analysis, non-parametric approaches were used such as the stratified, rank-based van Elteren test for continuous outcomes and the stratified Cochran-Mantel-Haenszel test for binary outcomes that account for stratification factors. In a further sensitivity analysis, the difference in postoperative VAS score for pain at 24 h, 48 h, and at discharge was adjusted for MC and use of adjunct analgesics. Furthermore, subgroup analyses were performed in the following strata: patients with spinal stenosis vs patients with herniated lumbar disc, baseline VAS score for pain < 5 vs patients with VAS ≥ 5, male vs female patients, patients aged ≤ 40 years vs > 40 years, patients with ASA classification ≤ II vs > II.

Results

Patients characteristics

Demographics and baseline characteristics are summarized in Table 1. There were no marked differences in patient characteristics. Between January 2015 and August 2016, 46 females and 54 males underwent elective lumbar spine surgery due to disc hernia (72%) or spinal stenosis (28%) with a median age of 61.5 years. No patient who underwent RA (n=50) experienced complications and none were switched to GA.

In the RA group, 42% of patients were female and 58% were male, 74% had a disc herniation and 26% had spinal stenosis. In the GA group, there was an equal number of women and men (50% each), 70% had a disc hernitiona and 30% had spinal stenosis. Fifty percent of the patients who underwent RA had a preoperative VAS score for pain ≥ 5 vs 56% in the GA group.

Primary endpoint

The mean postoperative MC at 48 h after surgery for all patients was 37.5 ± 24.2 mg. Over the first 48 h after the operation, RA patients received 34.3 ± 25.7 mg morphine vs 40.6 ± 22.3 mg morphine for the GA trial arm~~,~~ however, there was no significant difference between the two arms ($p = 0.197$, unadjusted).

For postoperative MC at 48 h, there was no significant interaction between the type of anaesthesia and any of the stratification factors (gender, age, ASA classification, VAS score for pain, or type of lumbar pathology).

Secondary endpoints

Intraoperative timepoints

Perioperative data and outcome variables are described in Table 2. Anaesthesia time and transition time were significantly shorter (both $p < 0.001$) in the RA group compared with the GA group (anaesthesia time:-125.4 ± 23.6 min for GA vs 99.4 ± 13.5 min for RA; transition time: 22.5 min for GA vs 10.0 min for RA). The surgery time was also significantly shorter (49.1 ± 13.0 min for RA vs 55.7 ± 16.0 min for GA, $p = 0.027$).

PONV, urinary catheter rate, length of stay in the PACU

Severity of PONV was not significantly different between the groups. In addition, the urinary catheter rate in the PACU and the median PACU length of stay did not significantly differ between groups (Table 2).

EQL-5D scores, patient satisfaction, surgeon satisfaction

There was a significant difference between the RA and GA groups in patient satisfaction. For RA, 16% of patients indicated a good and 84% a complete level of satisfaction, vs 26% for good and 74% for complete in the GA group ($p < 0.001$). Rates of complete surgeon satisfaction were 100% for GA and 90% for RA ($p = 0.256$). For the EQL-5D questionnaire, conducted at baseline and at 6 weeks after surgery, the RA and GA groups did not show a significant difference (Table 3).

Effects of anaesthesia technique, gender, and age on the VAS score for pain over time

VAS scores over time were significantly higher for females than for males (females, preoperative vs 6 weeks postoperative: 5.1 ± 2.8 vs 0.9 ± 1.3; men, preoperative vs 6 weeks postoperative: 3.6 ± 2.8 vs 0.5 ± 1.1, $p < 0.001$) at both time points (Table 4). Furthermore, the VAS scores for pain was lower for RA (0.1 ± 0.7) than GA (3.2 ± 3) at the start of the PACU stay ($p < 0.001$ for both crude and adjusted analyses) (Figure 2). No significant difference of pain intensity was found in younger patients (≤ 40 years) and the type of anaesthesia from the end of PACU up to 6 weeks after surgery (Table 4 and Table 5).

Discussion

This study confirms the results of previous trials on spinal anaesthesia as a safe and efficacious approach for lumbar spine surgery (4-6). In this study, RA was strongly associated with lower pain scores during the PACU stay, a shorter anaesthesia time and higher patient satisfaction. There was no statistically significant difference in MC within the first 48 hours after surgery. Above all, there have been suggestions that GA is a risk factor for development of postoperative delirium, and that this is not restricted to elderly patients (14, 15). The protocol for the present study did not specifically address the possibility of postoperative delirium, although the requirements AEs or severe AEs (SAEs) would still allow for detection. Based on the present study, however, no evidence was found for delirium in either the RA or GA group.

The finding of shorter anaesthesia time in the RA group was congruent with the current literature (4, 6-8, 13, 24). The slightly shorter surgery time with RA in the present study is also consistent with other reports by Jellish et al. (4) and Pierce et al. (24).

Similar to the results of the present study (100% complete surgeon satisfaction for GA vs 90% for RA), high patient and surgeon satisfaction for RA have been described in studies by Dagher et al. (2) and Attari et al. (17). In contrast, the results of Sadrolsadat et al. (5) and Kahveci et al. (13) showed lower surgeon satisfaction. However, the study by Sadrolsadat was a case-controlled study and not a prospective randomized trial (RCT).

In contrast to the present study, a lower rate of PONV in the RA group is strongly supported by several studies (6-8, 17, 18). Only Sadrolsadat et al. (5) have reported a higher percentage of patients experiencing PONV during the PACU stay after RA, but 1 day after the operation, the PONV rate was lower in the RA group. In contrast to the findings of Zorrilla-Vaca et al. (20), there was no reduction in the length of stay in the PACU unit in the RA group in this RCT.

In the present study, MC was not significantly higher at the 48 h postoperative time point in the GA group compared with the RA group. However, this result is difficult to compare with data in the current literature, details are sparse on the postoperative pain management used in most of the studies. Sadrolsadat et al. (5) and Attari et al. (2) reported less meperidine consumption for RA, but neither study specified the exact dosage over time nor the exact time course. McLain et al. (7) reported a similar pain management approach with intravenous morphine given in mg/h), but the total amount and the exact time period were again not specified.

There was no statistically significant difference between the RA and the GA group with regard to pain scores over time. The question of a difference between RA and GA with regard to pain scores ~~score~~ over time was not addressed in other studies (2, 4, 6-8, 13). Nevertheless, consistent with our data, Vural et al. (19) found no differences in VAS for pain scores 24 h after the operation. These findings were confirmed very recently by two meta-analyses, published by Zorrilla-Vaca et al. (20) and Meng et al. in 2017 (26). The meta-analyses showed that there was no statistically significant difference for postoperative pain scores with the two anaesthetic approaches in lumbar spine surgery (RA vs GA).

Publication of data by Zheng et al. (27) and Gerbershagen et al. (28) have enabled an analysis of perioperative risk factors (such as age and sex) and their influences on postoperative pain to be performed. There was a significant gender difference over time for the VAS score for pain ($p < 0.001$). However, there is known to be a gender difference in pain levels before and after treatment (21-23). Although females presented with higher baseline pain levels before an intervention, there was no gender difference after treatment (Peterson et al.) (21). The authors

of this publication discussed this mechanism as a “mystery”. Furthermore, females had a significantly higher VAS score for pain over time from the preoperative stage up to 6 weeks after the operation. The database by Tighe et al. (32) reflects the finding, of a higher baseline pain level in females. The final assessment reminded however unclear as discussed by Pereira et al. (33).

Limitations

There are some limitations in this RCT. Firstly, it is a single centre clinical trial with a lack of statistical power, due to the small size of the study population Secondly, in the RA group, intrathecal fentanyl was used. However, data are limited in the literature about its significance (29). Moreover, an intraoperative application of remifentanil in the GA group could have led to postoperative hyperanalgesia. However, these issues remain controversial based on the current literature (30, 31).

Conclusions

RA for elective lumbar spine surgery is a feasible and valuable alternative to GA. RA led to significantly shorter anaesthesia and transition time and higher patient satisfaction. There was some evidence for lower postoperative morphine consumption in the RA group, but the differences were not statistically significant. The gender influence in the perioperative phase and on postoperative pain relief remains unclear. Larger prospective RCT will be needed to determine the optimal perioperative protocols, and to resolve some of the confusions arising from heterogeneous data in the current literature.-The reduced transition time in RA may help to optimize the efficiency of surgical processes.

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Figure 1)

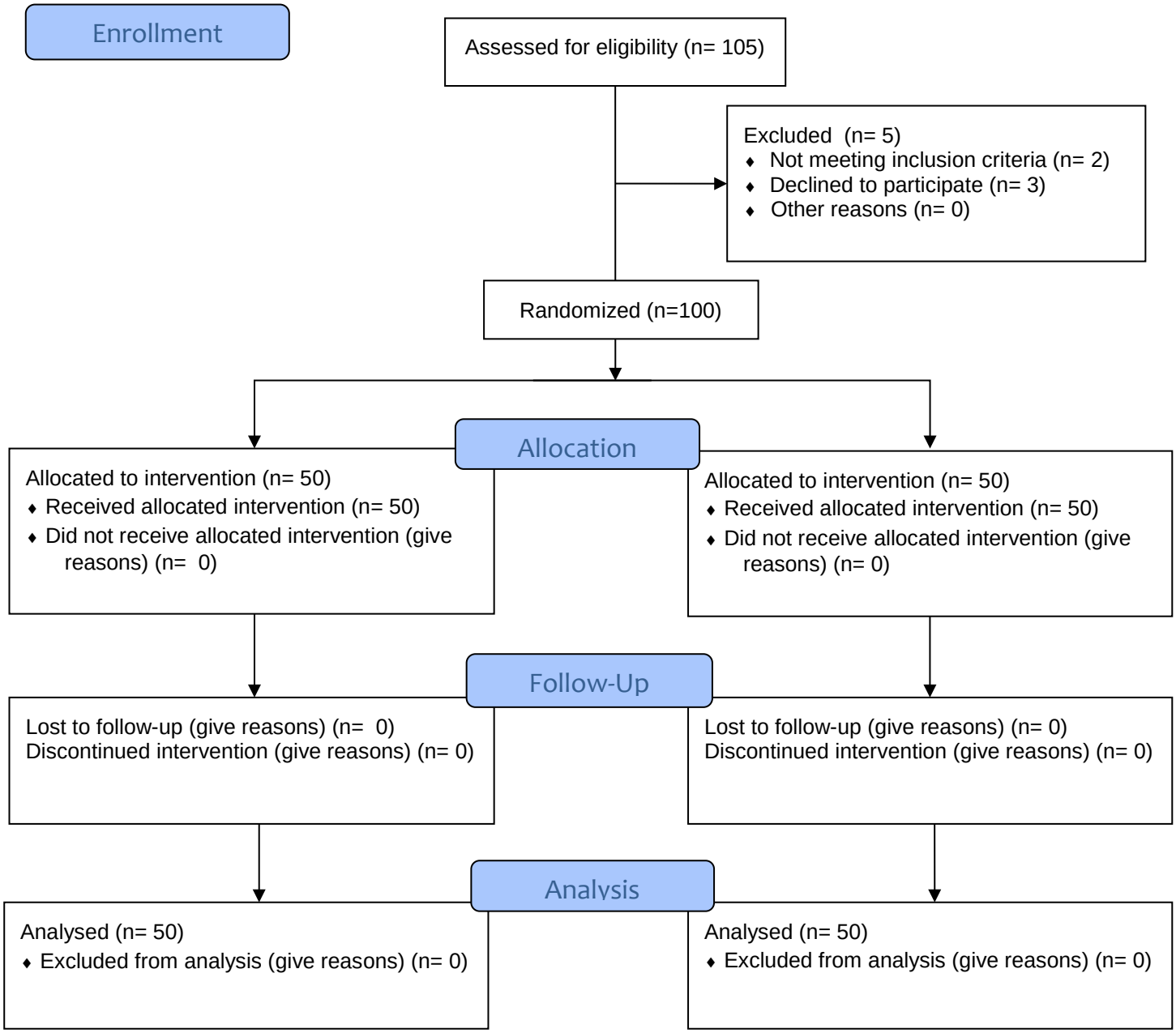
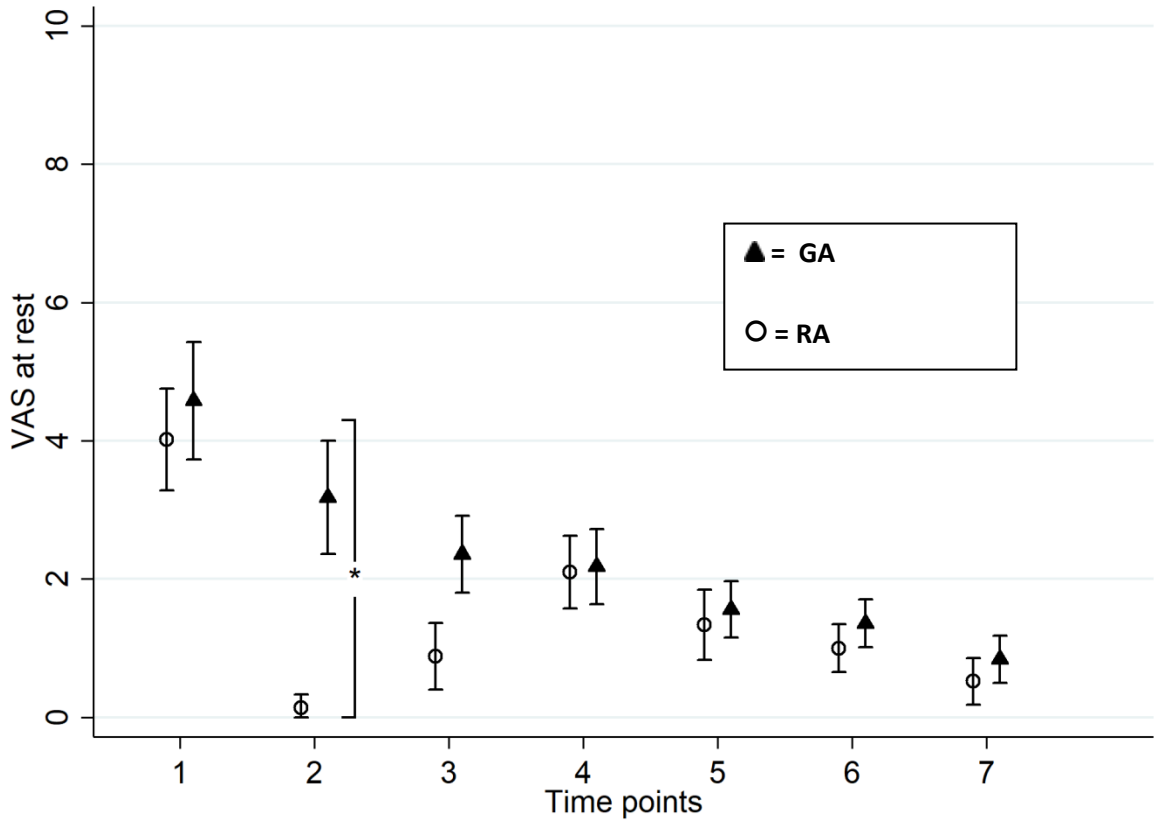

Enrollment
Assessed for eligibility (n= 105)
Excluded (n= 5)
♦ Not meeting inclusion criteria (n= 2)
♦ Declined to participate (n= 3)
♦ Other reasons (n= 0)
Randomized (n=100)
Allocation
Allocated to intervention (n= 50)
♦ Received allocated intervention (n= 50)
♦ Did not receive allocated intervention (give reasons) (n= 0)
Allocated to intervention (n= 50)
♦ Received allocated intervention (n= 50)
♦ Did not receive allocated intervention (give reasons) (n= 0)
Follow-Up
Lost to follow-up (give reasons) (n= 0)
Discontinued intervention (give reasons) (n= 0)
Lost to follow-up (give reasons) (n= 0)
Discontinued intervention (give reasons) (n= 0)
Analysis
Analysed (n= 50)
♦ Excluded from analysis (give reasons) (n= 0)
Analysed (n= 50)
♦ Excluded from analysis (give reasons) (n= 0)

Figure 2



Time Points: 1 = Pre-op; 2 = Start PACU; 3 = End PACU; 4 = 24 h post-op; 5 = 48 h post-op; 6 = Discharge; 7 = 6 weeks post-op.

Crude mean of VAS at rest pre-operatively until 6 weeks post-operatively with 95% confidence interval for GA (dark triangle) and RA (white circle) showing that RA lead to less pain postoperatively up to 2 days compared to GA. The asterisk (*) indicates a significant difference between the pain reported by patients operated using GA versus RA, when adjusted for type of operation (spinal stenosis or herniated lumbar disc) and VAS score at baseline < 5 versus VAS ≥ 5.

Table 1: Demographics and baseline characteristics

	Total group N = 100	GA N = 50	RA N = 50	p
Female	46 (46%)	25 (50%)	21 (42%)	0.547
Male	54 (54%)	25 (50%)	29 (58%)	
Age (years)*	61.5 (46.5; 72.0)	61.0 (48.8; 71.0)	62.5 (44.8; 75.3)	0.553
BMI	26.1 ± 4.4	26.9 ± 4.9	25.4 ± 3.7	0.07
Disc Hernia	72 (72%)	35 (49%)	37 (51%)	0.824
Spinal Stenosis	28 (28%)	15 (54%)	13 (46%)	
VAS at rest*	n = 100, 5.0 (2.0; 7.0)	5.0 (3.8; 7.0)	4.5 (1.8; 6.3)	0.186
VAS at rest ≥ 5	n = 100, 53 (53%)	28 (56%)	25 (50%)	0.689

*numbers represent median (interquartile range)

BMI Body Mass Index, VAS Visual Analogue Scale for pain

Table 2: Perioperative data and outcome variables

	GA N = 50	RA N = 50	p
Surgery time (min)	55.7 ± 16.0	49.1 ± 13.0	0.027
Transition time (min)*	22.5 (16.0; 25.0)	10.0 (6.8; 13.3)	<0.001
Anaesthesia time	125.4 ± 23.6	99.4 ± 13.5	<0.001
PACU time	100.6 ± 36.5	106.0 ± 40.3	0.426
PONV at start PACU			0.603
no PONV	47 (94%)	48 (96%)	
slight PONV	2 (4%)	2 (4%)	
moderate PONV	1 (2%)	0 (0%)	
strong PONV	0 (0%)	0 (0%)	
severe PONV	0 (0%)	0 (0%)	
Urinary Catheter rate	6 (12%)	6 (12%)	1.000
PONV at end PACU			0.563
no PONV	45 (90%)	47 (94%)	
slight PONV	2 (4%)	2 (4%)	
mooderate PONV	1 (2%)	1 (2%)	
strong PONV	2 (4%)	0 (0%)	
severe PONV	0 (0%)	0 (0%)	
PONV 24 h after surgery			0.280
no PONV	37 (74%)	44 (88%)	
slight PONV	4 (8%)	3 (6%)	
moderate PONV	5 (10%)	2 (4%)	
strong PONV	4 (8%)	1 (2%)	
severe PONV	0 (0%)	0 (0%)	
PONV 48 h after surgery			0.288
no PONV	44 (88%)	47 (94%)	
slight PONV	1 (2%)	1 (2%)	
moderate PONV	5 (10%)	1 (2%)	
strong PONV	0 (0%)	1 (2%)	
severe PONV	0 (0%)	0 (0%)	
LOS (days)*	4.0 (3.0; 5.0)	4.0 (3.0; 5.0)	0.614

*numbers represent median (interquartile range)

PACU Postoperative Anaesthetic Care Unit, PONV Postoperative Nausea Vomiting, LOS Length of Stay

Table 3: EQL, Patient and Surgeon Satisfaction

	GA	RA	p
EQL Baseline			0.564
no problem	0 (0%)	0 (0%)	
some problem	44 (88%)	42 (84%)	
extreme problem	6 (12%)	8 (16%)	
EQL 6 weeks after surgery			0.720
no problem	32 (64%)	30 (60%)	
some problem	17 (34%)	19 (38%)	
extreme problem	1 (2%)	1 (2%)	
Patient satisfaction			<0.001
no satisfaction	0 (0%)	0 (0%)	
little satisfaction	0 (0%)	0 (0%)	
good satisfaction	13 (26%)	8 (16%)	
complete satisfaction	37 (74%)	42 (84%)	
Surgeon satisfaction			0.256
no satisfaction	0 (0%)	0 (0%)	
little satisfaction	0 (0%)	0 (0%)	
good satisfaction	0 (0%)	5 (10%)	
complete satisfaction	50 (100%)	45 (90%)	

EQL European Quality of Life, GA General Anaesthesia, RA Regional Anesthesia

Table 4: VAS scores for pain over time

	Pre-op	Start PACU	End PACU	24 h postop.	48 h postop.	Discharge	6 weeks postop	Overall effect*	P*
All patients	4.3 ± 2.9	1.7 ± 2.6	1.6 ± 2.0	2.1 ± 1.9	1.5 ± 1.7	1.2 ± 1.3	0.7 ± 1.2		
GA	4.6 ± 3.1	3.2 ± 3.0	2.4 ± 2.0	2.2 ± 2.0	1.6 ± 1.5	1.4 ± 1.3	0.8 ± 1.2	-0.8 (-1.1 to -0.4)	0.230
RA	4.0 ± 2.7	0.1 ± 0.7	0.9 ± 1.7	2.1 ± 1.9	1.3 ± 1.8	1.0 ± 1.3	0.5 ± 1.2		
Male	3.6 ± 2.8	1.4 ± 2.3	1.5 ± 2.2	2.2 ± 1.8	1.4 ± 1.7	0.9 ± 0.9	0.5 ± 1.1	0.3 (-0.1 to 0.7)	<0.001
Female	5.1 ± 2.8	2.0 ± 3.0	1.7 ± 1.8	2.1 ± 2.0	1.5 ± 1.6	1.5 ± 1.6	0.9 ± 1.3		
Years >40	4.2 ± 2.9	1.5 ± 2.5	1.6 ± 2.1	2.2 ± 1.9	1.4 ± 1.7	1.2 ± 1.3	0.6 ± 1.1	0.3 (-0.2 to 0.9)	0.212
Years ≤40	4.9 ± 2.6	2.7 ± 3.1	1.8 ± 1.3	2.1 ± 2.0	1.8 ± 1.6	0.9 ± 1.0	0.9 ± 1.9		

*Adjusted for type of operation (spinal stenosis or herniated lumbar disc) and VAS score at baseline < 5 versus VAS ≥ 5.

VAS Visual Analogue Scale, GA General Anesthesia, RA Regional Anesthesia,
PACU Postoperative Anaesthetic Care Unit, ASA American Society of Anesthesiologists

Table 5: VAS scores for a pain over time (type of anaesthesia, crude and adjusted)

	Crude			Adjusted*	
	GA	RA	p	Treatment effect (95% CI)	p
T2 (start PACU)	3.2 ± 3	0.1 ± 0.7	<0.001	2.48 (1.49 to 3.47)	<0.001
T3 (end PACU)	2.4 ± 2	0.9 ± 1.7	<0.001	0.92 (-0.07 to 1.91)	0.069
T4 (24 h post-op)	2.2 ± 2	2.1 ± 1.9	0.836	-0.48 (-1.47 to 0.51)	0.343
T5 (48 post-op)	1.6 ± 1.5	1.3 ± 1.8	0.509	-0.34 (-1.33 to 0.65)	0.502
T6 (discharge)	1.4 ± 1.3	1 ± 1.3	0.156	-0.20 (-1.19 to 0.79)	0.693
T7 (6 weeks post-op)	0.8 ± 1.2	0.5 ± 1.2	0.195	-0.24 (-1.23 to 0.75)	0.636

*Adjusted for type of operation (spinal stenosis or disc herniation) and VAS score at baseline < 5 vs VAS ≥ 5

VAS Visual Analogue Scale, GA General Anesthesia, RA Regional Anesthesia, CI Confidence Interval, PACU Postoperative Anaesthetic Care Unit.