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ORIGINAL ARTICLE

P. Nordin · H. Hernell · M. Unosson
U. Gunnarsson · E. Nilsson

Type of anaesthesia and patient acceptance in groin hernia repair: A multicentre randomised trial

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Abstract *Background*: Groin hernia repair can be performed under general (GA), regional (RA), or local (LA) anaesthesia. This multicentre randomised trial evaluates patient acceptance, satisfaction, and quality of life with these three anaesthetic alternatives in hernia surgery. *Methods*: One hundred and thirty-eight patients at three hospitals were randomised to one of three groups, GA, RA, or LA. Upon discharge, they were asked to complete a specially designed questionnaire with items focusing on pain, discomfort, recovery, and overall satisfaction with the anaesthetic method used. The global quality-of-life instrument EuroQol was used for estimation of health perceived. *Results*: Significantly more patients in the LA group than in the RA group felt pain during surgery ($P < 0.001$). This pain was characterised as light or moderate and for the majority of LA patients was felt during infiltration of the anaesthetic agent. Postoperatively, patients in the LA group first felt pain significantly later than patients in the other two groups ($P = 0.012$) and significantly fewer LA patients consumed analgesics more than three times during the first postoperative day ($P = 0.002$). The results concerning nausea, vomiting, and time to first meal all favour LA. No difference was found among the three groups concerning overall satisfaction and quality of life. *Conclusion*: In a general surgical setting, we found LA to be well tolerated and associated with significant advantages compared to GA and RA.

Keywords Groin hernia repair · Anaesthesia · Patient acceptance · Quality of life · Randomised trial

P. Nordin (✉)
Department of Surgery, Östersund Hospital,
831 83 Östersund, Sweden
E-mail: par.nordin@jll.se
Tel.: +46-63-153000
Fax: +46-63-154527

H. Hernell · M. Unosson
Department of Medicine and Care Division of Nursing Science,
University of Health Sciences, Linköping, Sweden

U. Gunnarsson
Department of Surgery Mora Hospital,
University of Uppsala, Sweden

E. Nilsson
Department of Surgery, Motala Hospital,
Motala, Sweden

Introduction

Groin hernia surgery is one of the most frequent operations performed in general surgery. In outcome evaluation, incidence of recurrence and re-operation has previously overshadowed other considerations. However, the introduction of mesh techniques has led to a marked reduction in recurrence rates, and attention has now shifted to other aspects of hernia surgery in which evidence-based consensus is still lacking. For the important question of method of anaesthesia, there is still no consensus about the best choice. Whereas local anaesthesia is almost exclusively used in centres with a special interest in hernia surgery [1, 2, 3, 4], regional and general anaesthesia are preferred in routine surgical practice [5, 6, 7].

Most reviews and case series [8, 9, 10, 11, 12, 13] as well as randomised trials [14, 15, 16, 17, 18, 19, 20, 21, 22] indicate that LA has the edge on its rivals GA and RA. Its reported major advantages are: simplicity, safety for high-risk patients, extended postoperative analgesia, early mobilisation without postanaesthesia side effects, and low cost [2, 3, 4, 23]. These are, no doubt, important advantages, but we should not lose sight of the fact that for an operation to be entirely successful, the patient should be satisfied with all aspects of management. He is hardly likely to be so if he considers himself to have been exposed to more pain than was absolutely necessary. It is, therefore, worrying that several studies have reported frequent complaints of pain from patients operated upon under LA [8, 10, 12, 17, 21, 24], a drawback for which the surgeon's lack of familiarity with the technique is usually held responsible.

The aim of the present study was to compare the patients' acceptance and health-related quality of life with the three anaesthetic alternatives in general surgical practice.

Patients and methods

Between December 1999 and April 2001, 138 patients undergoing primary inguinal hernia repair were randomised to LA, RA, or GA. Three general surgical units at nonteaching hospitals—all aligned with the Swedish Hernia Register (SHR) [7], Östersund, Motala, and Mora—participated in the study.

All patients submitted to groin hernia repair, whether elective or as an emergency, were eligible for participation in the study. Exclusion criteria were: age under 18, femoral hernia, recurrent hernia, bilateral hernia, irreducible hernia, serious concomitant disease, bleeding disorder, and pregnancy.

Primary end points were intraoperative and postoperative pain, preoperative and intraoperative feelings of safety and security, nausea and/or emesis during (LA, RA) or after anaesthesia. Furthermore, patient acceptance and satisfaction, health-related quality of life, according to EuroQol [25], were studied. Secondary end points were: consumption of analgesics and recovery with regard to daily activities. The Regional Ethics Committees approved the study.

Surgeons and surgical technique

Surgeons with varying backgrounds and experience in hernia surgery performed the operations. They were free to make their own choice regarding method of repair, but an open technique with incision in the groin was mandatory (Table 1).

Randomisation

The randomisation process was performed using consecutively numbered sealed envelopes in batches of 18 (6×3), distributed to each participating unit by the coordinating study centre. After informed consent had been obtained, the envelope was opened prior to the start of anaesthesia and surgery.

Anaesthesia

Preoperative medication was administered according to local routine. At each of the participating hospitals, an experienced anaesthetist administrated or supervised RA and GA, also according to local routine. Addition of a local anaesthetic agent, infiltrated in the wound, was recommended for patients in these two groups. Incremental doses of analgesia and sedation during surgery were optional in the RA and LA groups. Conversion to GA was considered to have taken place if sedation had been so heavy as to lead to loss of consciousness. LA was performed by the surgeon, according to the local infiltration technique described by Amid et al. [23], using a 50:50 mixture of 1% mepivacain and 0.5% bupivacain as the anaesthetic agent. Participating surgeons were taught to perform the LA technique in a standardised manner during a 1-day course.

Postoperative care

For the great majority of patients, the operation was planned as an ambulatory procedure. They were discharged according to local routine, and painkillers were prescribed for unrestricted use up to the recommended maximal dosage. No restrictions concerning activities were given, and patients were encouraged to

Table 1 Preoperative data

	LA	RA	GA	Total
Randomised to (*n*)	40	52	46	138
Received anaesthesia (*n*)	38	55	45	138
Mean age (range)	58 (20–80)	56 (26–87)	56 (28–82)	57 (20–87)
Sex (*n*)				
Female	1	2	1	4
Male	39	50	45	134
Mean BMI (SD)	24.2 (3.0)	24.6 (2.6)	24.3 (2.8)	24.4 (2.8)
Emergency/elective (*n*)	0/40	0/52	1/45	1/138
Type of work (%)	*n* = 21	*n* = 31	*n* = 31	*n* = 83
Heavy	52	45	61	53
Light	24	39	26	30
Desk work	24	16	13	17
Pain from hernia (%)	70	76	85	77
Size of hernia (%)				
0–3 cm	44	40	26	36
4–7 cm	36	50	65	51
≥ 8 cm	21	10	9	13
Scrotal hernia (%)	21	16	11	16

BMI = body mass index; LA = local anaesthesia; RA = regional anaesthesia; GA = general anaesthesia

resume work and normal daily activities as soon as possible.

Questionnaire

Upon discharge, the patient was given a questionnaire with items covering pain before, during, and up to 7 days after their operation. Patients were also asked about consumption of analgesics (number/day), feeling of safety and security before and during the operation, presence of nausea and vomiting during (LA, RA) and after anaesthesia (yes/no), time to the first meal, restrictions of daily functions, and overall satisfaction with the procedure. Pain intensity was measured by means of an 11-point (0–10) numerical rating scale (NRS) with the extremes marked from "no pain to the worse pain possible". Mean postoperative pain and nausea scores while still at the hospital were estimated. The patients were taught how to handle the questionnaire, including the scale, before leaving the hospital. Eight days postoperatively, a specially trained nurse phoned the patient to supply any additional information regarding the questionnaire, if required.

Quality of life

The patients were also asked to complete a health-related quality-of-life questionnaire (EuroQol) preoperatively after 8 and 30 days, and 1 year postoperatively. The EuroQol [25] is a generic measure of health status that comprises five broad dimensions—patient mobility, self-care, activity, pain/discomfort, and mood—each with three categories scored from 1–3 (Table 2). In addition, patients are asked to compare their current health with their perceived health 12 months previously and to estimate their health on a "thermometer scale" (0–100).

Statistics and sample size

Statistical analyses were performed with the SPSS program (SPSS, Chicago, Ill. USA). Data were analysed according to the "intention to treat" principle. Hence, for the statistical analysis, converted cases were kept in their original groups.

Variables on a nominal scale, such as premedication, use of analgesics, etc., were compared with the $\chi 2$ test. P values stated are double-sided, and $P < 0.05$ was considered significant.

Quantitative variables, such as age and NRS values, were compared using the ANOVA test. Kruskal-Wallis tests were used when appropriate. Variables on the EuroQol questionnaire were compared with the McNemar test and the "thermometer scale" with Wilcoxon signed rank test.

With a two-sided significance level of 5% and a power of 80%, 40 patients in each group would detect a difference between 5 and 30% of binary data and a standardised difference (mean difference/standard deviation) of 0.7.

Results

Three patients were randomised to one method of anaesthesia but operated upon under another. One was converted, after the randomisation, from LA to RA because of pronounced anxiety. A second patient was converted from GA to RA because of a suspected neck tumour discovered at induction of anaesthesia, and a third patient was converted from LA to RA for reasons unclear. All three patients were kept in the groups to which they had originally been randomised. Thus, all data were analysed on an intention-to-treat basis (Table 1).

There were no serious intraoperative or postoperative complications.

Preoperative parameters

There were no significant differences among the groups with regard to age, sex, body mass index (BMI), emergency/elective operation, type of work, pain, size of hernia, and scrotal hernia (Table 1).

Before surgery, anxiety about anaesthesia was significantly more common among patients randomised to GA

Table 2 Intraoperative data

	LA ($n=40$)	RA ($n=52$)	GA ($n=46$)	Total ($n=138$)	P
Premedication (%)	68	77	77	75	NS
Complementary analgesia/sedation (%)	44	60		54	NS (0.146)
Infiltration in the wound (%)		68	89	78	0.018
Converted to GA [a](%)	2.6 ($n=1$)	18.0 ($n=9$)		11.4 ($n=10$)	0.024
Repair (n)					
Shouldice	3	3	3	9	
Other open nonmesh	0	2	1	3	
Open mesh	37	47	42	126	
Pain during surgery (mean NRS)	2.8	1.7		2.1	<0.001

[a] Patients required such heavy sedation/analgesic during surgery that they became unconscious and were therefore considered to have been converted to GA; NS = not significant; LA = local anaesthesia; RA = regional anaesthesia; GA = general anaesthesia; NRS = numerical rating scale

($P = 0.015$). However, a majority (80%) of all patients felt calm and secure immediately prior to induction.

Intraoperative parameters

Intraoperative parameters are shown in Table 3. Premedication was given less frequently to patients operated under LA, 68% compared with 77% for the RA and GA patients. These differences were not significant.

The methods of repair used were Lichtenstein (126), Shouldice (9), McVay (2), and Marcy (1). In patients who had regional anaesthesia, 43 (78%) had spinal anaesthesia, and 12 (22%) had epidural anaesthesia. The mean volume of local anaesthetic used (mean ± SD) in patients with LA was 41 ml ± 10 ml. Addition of a local anaesthetic agent infiltrated in the wound was significantly more frequently used in the GA group (89%) compared with RA, (68% $P < 0.018$).

Sixty percent of patients with RA required complementary analgesia and/or sedation, compared to 44% of the patients with LA ($P < 0.146$). One patient with LA (2.6%) and nine with RA (18.0%) required such heavy sedation that they became unconscious and were therefore considered as having been converted to GA. The difference between the RA and LA groups in this respect was significant ($P = 0.024$).

During surgery, significantly more patients in the LA group ($P < 0.001$) felt pain compared with the RA group. Among the patients in the LA group who felt pain during the operation, significantly more experienced pain during infiltration of the local anaesthetic agent ($P = 0.037$). A majority of patients judged their intraoperative pain as slight (NRS < 3), and the great majority of patients in the RA and LA groups felt calm and secure during the operation.

Postoperative parameters

As listed in Table 4, GA patients felt their first pain after surgery significantly earlier than patients in the other two groups ($P = 0.012$). In other respects, there were no significant differences among the groups regarding postoperative pain days 1–7 and number of days with considerable pain.

Concerning consumption of analgesics, significantly fewer patients in the LA group needed to take analgesics more than three times daily the first three postoperative days ($P = 0.002$). The difference in consumption of analgesics decreased over the next few days. There was no significant difference among the groups in total consumption and the mean number of days consuming analgesics.

Nausea and/or emesis during or after anaesthesia occurred in 36% of patients in the GA group, 28% in the RA group, and 13% in the LA group. However, the intergroup differences did not reach statistical

Table 4 Quality of life (EuroQol)

Mobility
1p—No problems in walking
2p—Some problems
3p—Confined to bed
Self-care
1p—No problems with self-care
2p—Some problems
3p—Unable to wash or dress self
Activity
1p—No problems with usual activities
2p—Some problems
3p—Unable to perform usual activities
Pain/discomfort
1p—No pain or discomfort
2p—Moderate pain or discomfort
3p—Extreme pain or discomfort
Anxiety/depression
1p—No anxiety or depression
2p—Some anxiety or depression
3p—Extreme anxiety or depression
Health status
1p—Improved
2p—Unchanged
3p—Impaired
Thermometer scale (0–100)
0 = The worst imaginable
100 = The best imaginable

Table 3 Postoperative data, pain, analgesics, and time to first meal

8-day questionnaire	LA ($n = 40$)	RA ($n = 52$)	GA ($n = 46$)	Total ($n = 138$)	P
Postoperative pain day 1–7 (mean NRS)					
Day 1	5.3	5.4	5.5		NS
Day 2	5.2	4.9	5.4		NS
Day 3	4.5	4.1	4.5		NS
Day 4	3.9	3.6	3.8		NS
Day 5	3.4	3.1	3.4		NS
Day 6	3.0	2.5	3.0		NS
Day 7	2.6	2.1	2.6		NS
First pain (mean hours)	3.5	3.5	2.7	3.2	$P = 0.012$
Postoperative days with considerable pain (mean)	3.9	4.0	4.3	4.1	NS
Mean number of days consuming analgesics (range)	4.4 (0–8)	4.4 (0–8)	4.7 (0–8)	4.5 (0–8)	NS
First meal (mean hours)	1.7	2.9	2.1	2.3	$P = 0.001$

LA = local anaesthesia; RA = regional anaesthesia; GA = general anaesthesia; NRS = numerical rating scale; NS = not significant

significance. Emesis did not occur at all in the LA group. Patients in the LA group could eat their first meal after surgery significantly earlier than GA and RA patients ($P = 0.001$). The mean time from end of operation to first meal was 1.7, 2.1 and 2.9 h for LA, GA, and RA patients, respectively. As regards daily activities, sleep, eating, and going to the toilet, there were no statistically significant differences among the groups 1 week after surgery.

There was no significant difference in overall satisfaction among patients in the three groups. A great majority of patients in all three groups were satisfied or very satisfied with their anaesthesia. In answer to the final question: ''Would you consider receiving the same type of anaesthesia again?'' 97% operated on under GA, 94% under RA, and 92% operated on under LA answered ''yes''.

Quality of life

Small differences among the three randomised groups were shown in quality of life, assessed with EuroQol questionnaires.. No statistically significant difference was found at any point for any of the variables. On the other hand, taking all three groups together, there was a clear difference between before and 1 year after surgery. For all compared variables, with the exception of anxiety/depression, patients gave significantly better scores 1 year after surgery than before. As regards general well-being estimated on the thermometer scale (0–100), the mean value had increased 11 units (95% CI 7–15).

Discussion

In the present trial, 46 patients were randomised to GA, 52 to RA, and 40 to LA, a divergence for which chance may well be held accountable. To obtain balance among the three methods compared, we sent envelopes for randomisation to the participating centres in batches of 18. The study was stopped on the same day, i.e. when each of the three centres was possibly in the middle of a batch. Consequently, the balance among the three methods was somewhat uneven.

The study focuses on the patient's experience of anaesthesia with a particular emphasis on pain during and after the operation. Significantly more patients in the LA group felt pain during the operation compared to the RA group. This difference is not surprising. RA, given by either subarachnoid (spinal) or epidural techniques, leads to a bilateral motor and sympathetic block, which normally provides good analgesia intraoperatively and in the immediate postoperative period. The LA method used in this study is a pure local infiltration technique, and the results concerning pain are probably more dependent on how conversant the surgeon is with the technique. The intraoperative pain in the LA group was, however, characterised as slight and most often occurred when the local anaesthetic agent was being infiltrated.

After the operation, however, patients operated upon under LA first felt pain significantly later on than did the other patients. Significantly fewer patients in the LA group used analgesics more than three times daily during the first days after surgery. Our results regarding intraoperative pain concur with several previous reports [8, 10, 12, 17, 21, 24]. As for postoperative pain, one study found no difference [13] between methods of anaesthesia, and six studies observed less pain with LA [8, 14, 16, 17, 19, 20, 22]. An exception is the randomised controlled trial of Teasdale et al. [21], in which patients with LA required more postoperative analgesia than those in the GA group. Perhaps their use of a short-acting agent may be have been the reason.

Comparison of postoperative aspects, such as nausea and vomiting, first meal, and daily activities, showed that local anaesthesia held the upper hand, as also reported by others [13, 20, 21]. A great majority of patients in all three groups were satisfied or very satisfied with the anaesthesia they had received, and 92% of LA patients would give their consent to a similar procedure if surgical correction of another hernia became necessary. In other investigations, the total satisfaction rate of patients operated on under LA varies between 80% and 96% [4, 8, 11, 19, 21].

When evaluating our results, it should be kept in mind that in randomised surgical trials, differences in the participating surgeons' experience with the methods compared may affect the outcome [26]. In the present trial, there was such a difference. The surgeons had been taught the LA technique during a 1-day course, and there was no pretrial examination. They can, therefore, hardly be regarded as very familiar with the technique, compared to the case for the other two arms of the comparison, where anaesthesia was given by or supervised by an experienced anaesthesiologist. Furthermore, we considered it unethical to withhold infiltration of a local anaesthetic agent entirely from patients in the GA and RA groups. Administration of a local anaesthetic agent in the wound was therefore recommended, but the decision was left to the discretion of the operating surgeon. The present comparison may thus be considered biased against local anaesthesia.

The infiltration in the wound was used significantly more frequently in the GA group (89%) compared with RA (68%). We don't believe this difference of a superficial infiltration of local anaesthesia can influence the postoperative results in any crucial way, since it does not, to our knowledge, prevent pain from deeper structures and the three involved nerves in the inguinal region.

According to numerous reports from specialised hernia centres, local anaesthesia may be used almost exclusively in open groin hernia repair [1, 2, 3, 4]. Data from national registers and epidemiological studies have shown that LA is used in only 5–18% of cases [5, 6, 7, 19]. Thus, there seems to exist a discrepancy between

existing scientific data and clinical practice. Reasons for this limited use could be the patient's wish to sleep because of fear of pain during surgery, the surgeon's desire for a relaxed operating area, or the reputation of LA because of a previous nonoptimal technique with unacceptable intraoperative pain as a consequence. Halsted and Cushing noted over 100 years ago that pain during surgery under local anaesthesia depends entirely upon the surgeon's familiarity with the technique, an experience that is presumably still valid today [24]. LA is only successful if the surgeon handles the tissues gently, has patience, and is fully conversant with the technique [10, 12]. When these conditions are fulfilled, surgeons should be able to offer the patient painless surgery, which no doubt is crucial for patient acceptance.

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