Local, regional, or general anaesthesia in groin hernia repair: multicentre randomised trial

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Summary

Background In specialised centres, local anaesthesia is almost always used in groin hernia surgery; whereas in routine surgical practice, regional or general anaesthesia are the methods of choice. In this three-arm multicentre randomised trial, we aimed to compare the three methods of anaesthesia and to determine the extent to which general surgeons can reproduce the excellent results obtained with local anaesthesia in specialised hernia centres.

Methods Between January, 1999, and December, 2001, 616 patients at ten hospitals, were randomly assigned to have either local, regional, or general anaesthesia. Primary endpoints were early and late postoperative complications. Secondary endpoints were duration of surgery and anaesthesia, length of postoperative hospital stay, and time to normal activity. Analysis was by intention to treat.

Findings Intraoperative tolerance for local anaesthesia was high. In the early postoperative period, local anaesthesia was superior to the other two types with respect to almost all endpoints. At 8 days' and 30 days' follow-up, there were no significant differences between the three groups. Although the mean duration of surgery was longer, the total anaesthesia time—ie, time from the start of anaesthesia until the patient left the operating room—was significantly shorter than it was for regional or general anaesthesia.

Interpretation Local anaesthesia has substantial advantages compared with regional or general anaesthesia, such as shorter duration of admission, less postoperative pain, and fewer micturition difficulties. The favourable results obtained with local anaesthesia in specialised hernia centres can, to a great extent, be reproduced by general surgeons in routine surgical practice.

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Introduction

For many years, groin hernia repair has been one of the most common operations worldwide. Yet, there is still no consensus about the best choice of anaesthesia. It is a sobering thought that little has changed since Halstedt and Cushing[1] introduced local anaesthesia for this kind of surgery more than 100 years ago. Thus, the present day surgeon faces almost the same choice as did his or her predecessors—the choice between local, regional, or general anaesthesia. Local anaesthesia is preferred at most centres where there is a special interest in hernia repair,[2–6] whereas in other settings, such as general surgical units, regional or general anaesthesia is more often used.[7–10] This discrepancy between the type of anaesthesia used has been explained by the type of surgeon doing the surgery—hernia repair done with local anaesthesia is supposed to require greater expertise and surgical skill and is, therefore, only successful if the surgeon is thoroughly familiar with the technique.[1,11]

In a randomised three-arm multicentre trial, we compared local, regional, and general anaesthesia in people who had hernia repair in non-specialised surgical practice. The need for such a study has recently been pointed out in an extensive review by Cheek and colleagues.[12]

Methods

Patients

Between January, 1999, and December, 2001, we screened all patients who were undergoing groin hernia repair, whether elective or as an emergency, in ten general surgical units at non-teaching hospitals for participation. Exclusion criteria were: age less than 18 years, recurrent hernia, femoral hernia, bilateral hernia, pregnancy, bleeding abnormalities, anticoagulant treatment, or a judgment that a patient was unfit for regional or general anaesthesia. Obesity, huge hernia, or scrotal hernia were not reasons for exclusion.

The regional Ethics Committee of each participating hospital approved the study. Patients received written information about the trial and gave verbal consent to participate.

Procedures

We randomly allocated patients to have local, regional, or general anaesthesia during their hernia repair. The randomisation process was done by use of random number sequences and consecutively numbered, sealed, opaque envelopes in blocks of 18 (6×3), distributed to each unit by the coordinating study centre. The envelope was opened before the start of anaesthesia and surgery.

All surgical units in the study were affiliated with the Swedish Hernia Register (SHR).[13] The operations were done by surgeons with varying backgrounds and experience in hernia surgery. Surgeons were free to use whichever open surgical technique they preferred, with or

without mesh, but the use of non-absorbable suture material was mandatory.

Primary endpoints were patient-related variables, pain, nausea, and postoperative complications at three timepoints—early postoperative (ie, time between leaving theatre and discharge from hospital), at 8 days' follow-up, and at 30 days' follow-up. Early complications were: bleeding necessitating reoperation or compression bandage, severe pain that necessitated the use of opioids, difficulties in micturition that required catheterisation. Duration of hospital stay and unplanned overnight admission was also recorded.

After days 8 and 30, we asked patients to complete a questionnaire about pain, postoperative use of analgesics, time to normal daily activity, and recontact, if any, with health-care providers within 30 days of surgery. Average pain (VAS) for the past week was scored after 8 and 30 days, respectively. A specially trained nurse phoned the patient for a follow-up interview about the VAS, complications, time to return to work, and level of normal daily activity. Patients with persistent discomfort or incomplete recovery had a clinical examination.

Secondary endpoints were: duration of anaesthesia and surgery, length of postoperative hospital stay, and number of days until normal activity could be resumed.

Anaesthetists administered regional and general anaesthetic in accordance with local routine. We recommended injection of local anaesthetic (10–20 mL bupivacain 2·5 mg/mL) into the wound, before or after the repair, for patients in these two groups. Local anaesthesia was done by the surgeon in accordance with the local infiltration technique described by Amid and colleagues,[14] and with a 50:50 mixture of 1% mepivacain and 0·5 % bupivacain. We gave pretrial training during a 1-day course at each participating hospital in which surgeons were taught to do the local anaesthetic technique in a standardised manner. Incremental doses of analgesia and sedation during surgery were optional for patients who had regional and local anaesthetic. Conversion to general anaesthetic was judged to have taken place if sedation had led to loss of consciousness. Preoperative and postoperative medications were administered in accordance with local routine.

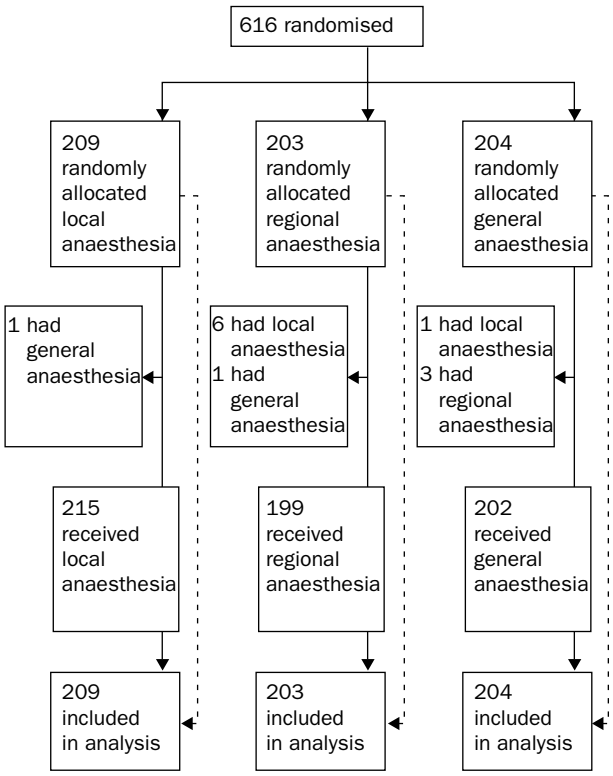
For most participants, the operation was planned as a day procedure. Patients were discharged in accordance with routine at their respective hospital. Use of painkillers was allowed up to the recommended maximum dose. We did not impose restrictions on patients' activities, and they were encouraged to resume work and normal daily activities as soon as possible.

Before surgery, we recorded age, body-mass index, type of usual work (heavy, light, or desk work), pain from the groin hernia, size of the hernia, and whether or not scrotal hernia was present.

During surgery, we recorded whether premedication had been given, use of intraoperative sedation, injection of local anaesthetic into the wound, duration of anaesthesia—ie, length of the patient's stay in the theatre from start of anaesthesia,—and duration of surgery.

Average pain and nausea during the postoperative hospital stay were estimated before discharge with a visual analogue scale (VAS); 1=no pain or nausea to 10=most severe.

Preoperative, perioperative, and postoperative data for all randomised hernia repairs were recorded continuously in accordance with the protocol, and we later transferred this information to a database. All data from study forms were checked and entered in the database twice, and errors were corrected. We also made random checks of data base information with patients' records and protocols from the Swedish Hernia Register. We did not do interim comparisons.



Trial profile

Statistical analysis

For calculation of sample size we used the formulas described by Campbell and colleagues.[15] With a complication rate of 35%, about 100 patients in each study group would be needed to detect a 50% change (relative risk <0·5 or >1·5). For continuous data, 176 patients in each group would be sufficient to identify a standardised difference defined as effect size (minimum difference accepted) divided by SD.

We used SPSS version 11.5 for statistical analyses. Analysis was by intention-to-treat. Hence, for the statistical analysis, converted cases were kept in their original groups.

Variables such as whether premedication was given, use of analgesics, and postoperative complications, were compared with the χ^2 test. p values were double-sided, and p values less than 0·05 were judged to be significant.

We compared quantitative variables, such as duration of surgery and anaesthesia, VAS values, and length of hospital stay using the ANOVA test.

Role of the funding source

The sponsor had no role in study design, data collection, data analysis, data interpretation, or in the writing of the report.

Results

After exclusion of patients who were allocated to surgeons not participating in the trial, who refused to participate, or who had a preference for one type of anaesthesia. Thus, 616 patients were included in final analyses (figure 1).

We aimed to record data for every patient operated on for hernia at the participating units, irrespective of whether

	Anaesthesia			Total (n=616)
	Local (n=209)	Regional (n=203)	General (n=204)	
Age (years)	57 (14)	55 (14)	56 (13)	56 (14)
Men	204 (98%)	200 (99%)	197 (97%)	601 (98%)
Body-mass index	25·2 (5·1)	25·0 (2·9)	24·8 (2·7)	25·0 (3·8)
Emergency/elective ratio	2/207	0/203	2/202	4/612
Type of work	n=122	n=117	n=119	n=358
Heavy	67 (55%)	49 (42%)	62 (52%)	178 (50%)
Light	35 (29%)	43 (37%)	34 (29%)	112 (31%)
Desk work	20 (16%)	25 (21%)	23 (19%)	68 (19%)
Pain from hernia	159 (77%)	157 (80%)	155 (78%)	469 (78%)
Size of hernia				
0–3 cm	67 (32%)	60 (31%)	58 (29%)	185 (31%)
4–7 cm	112 (55%)	120 (61%)	120 (61%)	352 (59%)
⩾8 cm	27 (13%)	16 (8%)	20 (10%)	63 (10%)
Scrotal hernia	26 (13%)	18 (9%)	20 (10%)	64 (11%)

Data are mean (SD) or number (%).

Table 1: **Baseline characteristics**

they were included in the study, to identify study selection mechanisms and, hence, external validity of the trial. Unfortunately, however, the response rate for non-randomised patients was too low for valid conclusions to be drawn.

12 patients were randomised to one anaesthetic method but operated on with another. One patient was converted from local to general anaesthesia because of pronounced anxiety. One patient assigned to the general anaesthesia group was given local anaesthesia because of high blood pressure, and another was converted from general to regional anaesthesia because of a suspected neck tumour discovered at induction of anaesthesia. Reasons for a different type of anaesthesia being given to that which was assigned were unclear in nine patients. Seven of these nine were randomised to regional anaesthesia, but had their operation with local anaesthesia in six cases and general anaesthesia in one. Two patients were randomised to general anaesthesia, but were given regional anaesthesia. Data for all twelve patients were analysed in the groups to which they had originally been randomised—ie, as per an intention-to-treat approach. Table 1 shows patients' characteristics. Preoperative data did not differ between groups, which suggests that randomisation procedures were adhered to.

456 (74%) patients had premedication, with no difference between groups (table 2). In patients who had regional anaesthesia, 161 (82%) had spinal anaesthesia, and 35 (18%) had epidural anaesthesia. Mean volume of local anaesthetic used in the local anaesthesia patients was 42 mL (SD 11). Table 2 shows method of repair, intraoperative sedation, addition of local anaesthetic in the wound, time for anaesthesia, and duration of surgery. Mean duration of surgery done with local anaesthesia was significantly longer than with general anaesthesia or regional anaesthesia. By contrast, time for anaesthesia was shorter with local anaesthesia than with regional anaesthesia and general anaesthesia.

Method of repair was well matched between the groups. There were no serious perioperative complications.

Four patients who had local anaesthesia (1·9%) and 19 who had regional anaesthesia (9·6%) required such heavy sedation that they became unconscious and were therefore judged to have had general anaesthesia, and this difference was significant (p=0·001) (table 2).

Postoperative data are shown in table 3. People who had local anaesthesia reported significantly less pain and nausea in the early postoperative period than those in the other two groups; pain scores were highest for patients who had general anaesthesia (table 3). 67 (34%) and 43 (22%) patients needed opioid analgesics in the general and regional anaesthesia groups, respectively, compared with only 17 (8%) of those who had local anaesthesia.

Overall, the frequency of early postoperative complications was significantly higher in patients who had general and regional anaesthesia than in those who had local anaesthesia. Of patients who had regional anaesthesia, 29% had to be catheterised after the operation because of micturition difficulties compared with only 8% of patients who had a general anaesthesia and none who had local anaesthesia. There was no difference between groups with respect to postoperative bleeding.

Mean postoperative time spent in hospital was significantly shorter after local anaesthesia than after general anaesthesia or regional anaesthesia. Patients who had had local anaesthesia also had a much lower rate of unplanned overnight admissions than did people who had regional or general anaesthesia (table 3).

Table 3 shows the results of the telephone follow-up interview 8 days after surgery. The occurrence of pain during the first 8 days and postoperative consumption of analgesics did not differ greatly between groups.

We did not note any significant difference between the groups with respect to complications; however, significantly more patients who had regional anaesthesia needed a return visit to a doctor. About a third of all patients could return to normal activity within the first 8 days, irrespective of the method of anaesthesia used.

	Anaesthesia			Total (n=616)	p
	Local (n=209)	Regional (n=203)	General (n=204)		
Premedication received	154 (74%)	154 (76%)	148 (73%)	456 (74%)	0·88
Completion of analgesic/sedation	110 (55%)	108 (56%)	NA	218 (56%)	0·84
Infiltration in the wound	NA	101 (56%)	152 (83%)	253 (70%)	<0·0001
Converted to general anaesthesia*	4 (2%)	19 (10%)	NA	23 (6%)	0·0001
Mean duration (min) of surgery (95% CI)	69 (67–72)	62 (59–65)	60 (57–63)	64 (62–66)	<0·0001‡
Mean time (min) for anaesthesia(95% CI)	90 (87–93)	100 (96–104)	95 (91–98)	95 (93–97)	<0·0001§
Repair†					
Shouldice	15 (7%)	16 (8%)	16 (8%)	47 (8%)	
Other open non-mesh	1 (0%)	4 (2%)	2 (1%)	7 (1%)	
Open mesh	182 (88%)	171 (84%)	172 (84%)	525 (85%)	
Plug	10 (5%)	12 (6%)	14 (7%)	36 (6%)	

NA=not applicable. Data are number (%) unless otherwise stated. For three-way comparisons with p>0·05, paired analyses were not done. *Patients required such heavy sedation during surgery that they became unconscious and considered to have converted to general anaesthesia. †Data missing for one patient who had local anaesthesia. ‡Local *vs* regional and local *vs* general. §Local *vs* regional.

Table 2: **Intraoperative data**

	Anaesthesia			Total	p
	Local	Regional	General		
Early post-operative data	n=205	n=198	n=199	n=602	
Mean pain, VAS score 1–10 (95% CI)	1·8 (1·6-2·0)	3·0 (2·7–3·2)	3·3 (3·0–3·5)	2·7 (2·6–2·8)	<0·0001*
Mean nausea, VAS score 1–10 (95% CI)	1·1 (1·0–1·1)	1·3 (1·1–1·4)	1·7 (1·5–1·9)	1·3 (1·2–1·4)	<0·0001*
Early complications	30 (15%)	95 (48%)	87 (44%)	212 (35%)	<0·0001*
Postoperative bleeding	13 (6%)	6 (3%)	13 (6%)	32 (5%)	
Pain required opioids	17 (8%)	43 (22%)	67 (34%)	127 (21%)	
Catheterised	0	57 (29%)	15 (8%)	72 (12%)	
Mean in-hospital stay (h) (95% CI)	3·1 (2·8–3·4)	6·2 (5·6–6·8)	6·2 (5·5–6·8)	5·1 (4·8–5·4)	<0·0001*
Unplanned overnight admission	7 (3%)	27 (14%)	44 (22%)	78 (13%)	<0·0001*
Questionnaire at 8 days	n=197	n=191	n=191	n=579	
Mean pain, VAS score 1–10 (95%CI)	3·8 (3·5–4·1)	4·1(3·8–4·3)	4·0 (3·7–4·3)	4·0 (3·8–4·1)	0·57
Still had considerable pain (%)	19 (9·8%)	22 (11·6%)	26 (13·6%)	67 (11·7%)	0·50
Mean days consuming analgesics (range)	3·1 (0–8)	3·8 (0–8)	3·5 (0–8)	3·4 (0–8)	0·10
Phone-call at 8 days	n=197	n=182	n=188	n=567	
Complications	80 (41%)	90 (50%)	91 (48%)	261 (46%)	0·16
Haematoma	35 (18%)	38 (21%)	42 (22%)	115 (20%)	
Infection	14 (7%)	6 (3%)	12 (6%)	34 (6%)	
Testicular swelling	13 (6%)	9 (5%)	13 (7%)	35 (6%)	
Other	26 (13%)	44 (24%)	36 (19%)	106(19%)	
Had returned to normal activity (%)	65 (33%)	55 (30%)	61 (32%)	181(32%)	0·80
Questionnaire at 30 days	n=193	n=187	n=187	n=567	
Mean average pain VAS score 1–10 (95% CI)	1·1 (0·9–1·3)	1·3 (1·1–1·6)	1·1 (0·9–1·3)	1·2 (1·1–1·3)	0·33
Mean time to normal daily activity (95% CI)	9 (8–10)	9 (8–10)	10 (9–11)	9 (9–10)	0·97
Mean time to leisure activity (days) (95% CI)	14 (13–15)	16 (15–17)	15 (14–17)	15 (14–16)	0·16
Contact with health service					
Nurse	35 (18%)	34 (18%)	41 (22%)	110 (20%)	>0·05
Doctor	22 (11%)	21 (11%)	22 (12%)	65 (12%)	>0·05
Emergency department	11 (6%)	11 (6%)	4 (2%)	26 (5%)	0·52
Readmission	1 (1%)	1 (1%)	2 (1%)	4 (1%)	0·73
Phone-call at 30 days	n=204	n=184	n=191	n=579	
Complication	61 (29%)	45 (25%)	45 (24%)	151 (26%)	0·30
Infection	6 (3%)	5 (3%)	7 (4%)	18 (3%)	
Considerable pain	16 (8%)	9 (5%)	7 (4%)	32 (6%)	
Testicular swelling	8 (4%)	3 (2%)	4 (2%)	15 (3%)	
Other	39 (19%)	29 (16%)	29 (17%)	97 (17%)	
Mean days for return to work (95% CI)	13† (12–15)	14‡ (12–15)	14§ (12–15)	14¶ (12–15)	0·96

Data are n (%) unless otherwise indicated. For three-way comparisons with p>0·05, paired analyses were not done. *Local *vs* regional and local *vs* general. †n=94. ‡n=91. §n=86. ¶n=271.

Table 3: **Postoperative follow-up data**

All results from the telephone follow-up at 30 days are shown in table 3. VAS scores for average pain during the 30 days did not differ greatly between groups, and showed a striking improvement compared with pain reported during the first 8 days.

No significant differences were noted between groups for complications within 30 days of surgery. Mean time to normal daily activity was around 9 days (SD 7), and mean time to resume leisure activity was about 15 days (9), with no differences between groups. Likewise, there was no difference with respect to time to return to work (mean 14 days). Somewhat less than a fifth (110) of all patients needed nurse care, 65 (12%) visited a doctor, 26 (5%) presented at the emergency department, and 4 (1%) patients were readmitted.

Discussion

In our randomised trial, local anaesthesia given by general surgeons who had had 1 day of instruction was associated with less time spent by the patient in theatre, shorter duration of hospital stay, less postoperative pain, and fewer micturition difficulties than were either regional or general anaesthesia.

Our trial was part of the Swedish Hernia Register's general objective to explore ways to achieve optimum results and minimum costs for groin hernia surgery. We had been intrigued by findings from several other studies—namely, the superior results obtained with local anaesthesia reported from specialised hernia clinics.[2–6] Such results are usually explained by the importance of skill in surgery—ie, increased experience is certain to lead to better results.[16] However, it might be that the superior results are attributable not only to the specialised surgeon's greater skill, but also to the anaesthesia method used. This is the hypothesis we have tested.

Surgeons of varying backgrounds and experience participated in the trial. Moreover, surgeons were free to use their preferred method of hernia repair so that conditions in our trial matched those in general surgical practice, increasing the general validity of our conclusions.

Have we made an impartial comparison of the three methods of anaesthesia? We believe so. Regional and general anaesthesia were already established procedures at the participating centres, whereas local anaesthesia for hernia repair was a new concept. One investigator (PN) taught the local anaesthesia method at a 1-day visit to each participating hospital, where surgeons were shown how to do the technique in a standardised manner. Trial conditions were, thus, not biased in favour of local anaesthesia; in fact, bias in the opposite direction would seem more likely.

Our results show that the use of local infiltration for groin hernia repair has substantial advantages over both regional and general anaesthesia. Noticeable in the intraoperative variables was the high tolerance of surgery in patients who had local anaesthesia. Just under 2% of patients required such heavy sedation that they were reclassified as having converted to general anaesthesia. The corresponding rate for patients who had regional anaesthesia was significantly higher—almost 10%.

Duration of surgery with local anaesthesia was significantly longer than for the other groups and also longer than that reported in two previous trials,[17,18] but shorter than that reported by Song and colleagues.[19] The longer time in theatre associated with local anaesthesia was compensated for by the significantly shorter time for anaesthesia, compared with regional and general anaesthesia.

Postoperative side-effects and prolonged hospital stay after groin hernia surgery are often related to the effects of anaesthesia. The advantages of local anaesthesia in the early postoperative course were noteworthy. For almost all variables, local anaesthesia had much better results than did its alternatives. This advantage remained for length of postoperative hospital stay and for number of unplanned overnight admissions, which was only half the rate reported after regional and general anaesthesia. The main reason for prolonged hospital stay was, we assume, greater postoperative pain as shown by the rate of people for whom opioid analgesics were necessary after regional and general anaesthesia. Especially of note, however, was the large number of patients, especially in the regional anaesthesia group, who had a high rate of micturition difficulties, severe enough to necessitate urethral catheterisation. Average pain and nausea during the postoperative hospital stay was estimated just before discharge. This time did differ between the groups since patients in the local anaesthesia group were discharged a mean of 3 h earlier than were the other patients, which should be kept in mind when assessing our results.

At 8 days' and 30 days' follow-up, there were no significant differences between the groups with respect to pain, consumption of analgesics, complications, time to normal daily activity, and time until return to work. Not surprisingly, differences between the three methods are most striking during the early postoperative period and tend to disappear with time. The high rate of complications at the 8 day telephone follow-up was probably a result of our interview design, which meant that even slight postoperative problems might have been classified as complications.

Many other investigators have also noted advantages of local anaesthesia.[5,17–28] We are aware of five randomised trials that compare general anaesthesia with local anaesthesia,[17,18,23,26–28] and three that compare all three methods.[19,24,25] Results of four of these studies showed significantly less pain after local anaesthesia,[17,19,26–28] whereas two did not show any difference.[23,24] However, none of these studies had the power of our trial. There is more unanimity with respect to the frequency of urinary retention. Investigators from several series and randomised studies have noted this difficulty to be infrequent with local infiltration when compared with the rates associated with general and, especially, regional anaesthesia.[4,5,9,19,29]

Our results show that local anaesthesia has substantial advantages over regional and general anaesthesia. Furthermore, good outcomes achieved with local anaesthesia in specialist hernia centres can be reproduced by general surgeons in routine surgical practice.

Participating units

The following surgical units (with surgeon and co-worker) participated in the study—Motala (E Nilsson, A Fredäng), Mora (R Heuman, K Lindblom), Kalmar (P Möller, A Hansson), Östersund (P Nordin, A C Norberg), Säffle (M Berne, B Olsson), Lidköping (J Tängström, N Fahl), Falköping (B Novik, U Mörk), Skene (L-Å Åkesson, I Snygg), Kalix (U Hyvönen, T Parkkinen), Varberg (M Campanello, I Källerteg).

Contributors

P Nordin and E Nilsson had the original study idea, initiated and coordinated the study, and designed the protocol. P Nordin taught the local anaesthesia method at a 1-day visit to each hospital, and wrote the drafts of the manuscript. U Gunnarsson helped design the protocol, and H Zetterström provided the anaesthetic perspective. All investigators contributed to the interpretation of results and revision of the manuscript.

Conflict of interest statement

None declared.

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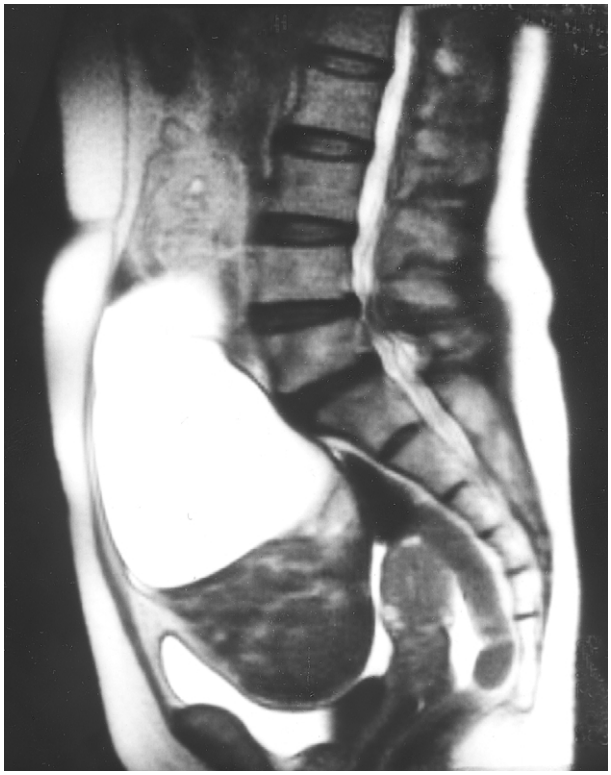
Clinical picture

Brenner tumour

Satoru Yoshida, Mitsuo Shidoh, Yasuharu Shimoya, Yuko Ohta



A 60-year-old woman presented with a 2-month history of lower abdominal distention but no history of weight loss. Tumour markers including CA 125 and CA 19-9 were normal. Ultrasonography and subsequent MRI of the pelvis showed a large pelvic mass with mixed solid and cystic components apart from the uterus. The solid component showed low signal intensity on T2-weighted images, indicating an abundance of fibrous tissues (figure). At surgery, a mass with a well defined margin was found arising from the left adnexa. The specimen was confirmed to be a benign Brenner tumour—a rare epithelial neoplasm of the ovary. The patient had an uneventful postoperative course.

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