Closed Drainage versus Non-drainage for Single-level Lumbar Discectomy: a prospective randomized controlled study

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Abstract

Background In spine surgery, postoperative epidural hematoma and wound infections can have devastating neurologic compromise. Closed drainage is commonly used for prevention of postoperative hematoma, infection, and associated neurologic impairment after lumbar decompression, but it remains unclear whether closed drainage reduces postoperative complications and improves clinical outcomes or not. The purpose of this study was to determine the efficacy of closed drainage in reducing complications and improving clinical outcomes after single-level lumbar discectomy.

Methods 420 patients with single-level lumbar disc herniation were recruited between March 2012 and March 2015 (169 females and 251 males, age 50.0±6.4 years). Patients were randomly assigned to either closed drainage group (214 patients) or non-drainage group (206 patients). The rates of postoperative complications (fever, symptomatic epidural hematoma, wound infections, and requiring revision surgery) were compared between the two groups using a chi square test or Fisher exact test. Pain intensity was evaluated by VAS. Functional ability was measured for all the patients using ODI. The lower extremity VAS score and ODI score were evaluated preoperatively, postoperatively, and at the last follow-up. The operation area VAS scores were evaluated preoperative, postoperative day 1, week 1, week 2, month 1, and at the last follow-up. The scoring results were compared between the two groups using a t test.

Results The difference in postoperative fever between patients in the closed drainage group (18.7%) and non-drainage group (28.2%) was statistically significant ($p < 0.05$). This is mainly due to the difference of patients with fever less than 38.5 °C . There was no significant difference in symptomatic epidural hematoma, infection rate, and re-operation rate when the two groups were compared. Only compared the postoperative day 1 operation area VAS score, the closed drainage group (5.1±0.8) was better than the non-drainage group (6.0±0.7) and with a significant statistical difference ($p < 0.05$). The left scoring results compared between the two groups were not significant difference ($p > 0.05$).

Conclusions We believe that closed drainage can be beneficial to reduce postoperative fever rate and alleviate postoperative operation area pain in the early postoperative period, but it has no effect on preventing postoperative occurrence of symptomatic epidural hematoma, wound infections, need for revision surgery; and improving clinical outcomes in single-level lumbar discectomy.

Introduction

Surgeons have been using postoperative drainage for generations [1]. The use of drains in medicine has been dated back as far as the ancient Egyptians. Hippocrates was the first to describe the use of hollow tubes for drainage of surgical wounds (460 – 377 B.C.) [2]. Closed drainage has been commonly used in orthopedic surgery, particularly in spine surgery, principally in order to prevent the formation of hematoma [1, 3–5], and considering hematoma provides an excellent culture medium for infections, evacuation of hematoma is considered advisable to prevent postoperative infections [3, 6].

Although the long history of drain usage, however, using of drainage after surgery is rarely supported in the scientific literature. Drains have not been shown to provide benefit with respect to rates of infection and hematoma in fracture or trauma surgeries [7, 8]. Some of retrospective studies have suggested that drains may be unnecessary in operations on the spine [3]. It is difficult to dispute the seemingly logical concept of wound drainage. The empiric uses of drains to avoid postoperative hematoma formation, then, is called into question [1]. In spine surgery, postoperative epidural hematoma and wound infections can have devastating neurologic compromise [9–14]. Mohi et al [15] and Mirzai et al [6] reported that epidural hematoma on the first postoperative day of lumbar disc surgery occurred as frequently as 86–89% after using MRI scan. For such a high incidence of hematoma, however, the vast majority of hematoma do not have any effect on the patient, symptomatic epidural hematoma is uncommon after lumbar disc surgery. The quoted incidence of post-surgical symptomatic epidural hematoma occurring after all spinal procedures requiring surgical intervention ranges from 0.2–2.9% [3, 6, 16].

As a result, closed drainage is commonly used for prevention of postoperative hematoma, infection, and associated neurologic impairment after lumbar decompression, but it remains unclear whether closed drainage reduces postoperative complications and improves clinical outcomes or not. In order to answer these questions, this prospective, randomized study was designed to determine the efficacy of prophylactic closed drainage in improving clinical outcomes after single-level lumbar discectomy.

Methods

Patients with single-level lumbar disc herniation were allocated to either closed drainage group or non-drainage group during a 3-year period (between March 2012 and March 2015). The ethics committee of our medical center approved the study protocol and patients provided written informed consent before participation. The authors confirm that all ongoing and related trials for this intervention are registered. Since our research center had not registered before the start of the study, there was a delay in registration.

The diagnosis of lumbar disc herniation was based on preoperative symptoms, clinical examination, and spinal nerve root compression detected by magnetic resonance imaging (MRI) examination [17]. Indications for lumbar discectomy surgery to disc herniation patients were extensive or unbearable pain radiating down to the lower extremity and/or muscle weakness with ineffective conservative treatment and, in majority of patients, a positive straight leg raising test gave a value of < 60 degrees. Patients may also have presented loss of Achilles reflex, cauda equina syndrome and/or regional sensory loss.

Inclusion criteria were: patients with single-level lumbar disc herniation in accordance with surgical indications. Exclusion criteria were: patients with abnormal international normalized ratios or activated partial thromboplastin time (APTT) or count fibrinogen or partial thromboplastin time (PTT), preoperative use of anticoagulant or antiplatelet drugs, or had any known bleeding disorder (thrombocytopenia, coagulation factor deficiency), history of diabetes, senile psychosis, cerebral disease with cognitive damage, malignant tumor, metabolic osteopathy, spinal infection, dermatosis, cerebrospinal fluid leak due to dural injury during the operation, and patients with previous surgery on the herniated disc segment or with other spinal disorders. There were 169 female and 251 male patients included in this study, with a mean age of 50.0 ± 6.4 years (range 27 to 64 years). Preoperative lumbar disc herniation was detected at the level L3/L4 in 39 (9.3%) cases, L4/L5 in 208 (49.5%) cases, and L5/S1 in 173 (41.2%) cases. The patients were randomly assigned to either closed drainage group (214 patients) or non-drainage group (206 patients). A schematic diagram of this study design is shown in Fig. 1, with demographic information about the patients who were present at final follow-up is given in Table 1.

Antibiotics were given to all patients, prophylactically. 30 minutes before the incision, systemic prophylactic antibiotic therapy with cefazolin was administered intravenously in a dosage of 2 grams and 2 grams every 12 hours until 24 hours postoperatively. However, clindamycin was used in patients with positive cephalosporin skin test.

All discectomies were performed for a virgin (unexplored) single-level by the same surgeon using a standard technique. The surgical technique was as follows: After general anesthesia with endotracheal intubation, the patient was placed in prone position. Use the C-arm to confirm the position of herniated disc and make the skin markers. Following a mid-line skin incision of about 3–5 cm extending from the spinous process above the involved level to the spinous process below, dissection was carried down to the fascia. The fascia was incised, and the paravertebral muscles were then dissected off the laminae in a subperiosteal fashion unilaterally. After complete exposure, a partial hemilaminectomy was performed and the ligamentum flavum was opened enough to expose the dural sac, the compromised nerve root, and the entire disc herniation. Epidural hemostasis was achieved with temporary compression and bipolar coagulation when necessary in all patients in both groups. The disc was then removed with the nerve root carefully retracted medially.

When the operative procedure is over, before closing the wound, the surgeon withdrew a card from a sealed envelope which had been prospectively prepared and randomized at the outset of the operation. The envelope says "drainage" or "no drainage", which will determine whether patients will be randomly divided into "closed drainage group" or "no drainage group". The wound closure was the same in both groups except for different drainage methods. Gravity drainage device was used in the drainage group. If dural tear occurs during surgery, patients will be excluded from the study. Although these patients were initially included to participation in the study, they received drains were excluded from the randomization process, and were not included in the final study results.

If the drainage had been less than 50 milliliters in the previous 24 hours, the drain was removed. All drains were withdrawn in 24 or 48 hours postoperatively. Before the removal of drainage tube, all the drainage group patients received a few drainage fluid collections for bacterial culture and drug sensitivity test to detect and treat infection risk factors as early as possible. At the time of drain withdrawal, the amount of hemorrhagic collection was between 28 and 150 milliliters, with an average of 54.2 ± 15.5 milliliters.

The postoperative clinical follow-up period was 2 years. The rates of postoperative complications (fever, symptomatic epidural hematoma, wound infections, and requiring revision surgery) were compared between the two groups using a chi square test or Fisher exact test. Pain intensity was evaluated by visual analog scale (VAS). Functional ability was measured for all of the patients using the Oswestry Disability Index (ODI). Postoperative evaluation pain and functional ability as measured by the VAS and ODI were obtained at the time of discharge. The lower extremity VAS score and ODI score were evaluated preoperatively, postoperatively, and at the last follow-up. The operation area VAS score were evaluated preoperatively, postoperative day 1, week 1, week 2, month 1, and at the last follow-up. The scoring results were compared between the two groups using a t test. Quantitative results were presented as mean ± standard deviation. Data were analyzed using SPSS version 19.0 statistical software (SPSS, Chicago, IL, USA). Bilateral $p < 0.05$ was considered statistically significant.

Results

Demographic characteristics of patients

With respect to mean age, operation time, and intraoperative blood loss, the differences between patients in the closed drainage group and those in the non-drainage group were not statistically significant ($p > 0.05$) (Table 1).

Primary Results

In both groups, a total of 98 patients (23.3%) developed fever postoperatively. The difference in postoperative fever between patients in closed drainage group (18.7%) and non-drainage group (28.2%) was statistically significant ($p < 0.05$). Making a concrete analysis, in the closed drainage group, 38 (95.0%) of the 40 febrile patients were less than 38.5 degrees, and the remaining 2 (5.0%) patients were greater than 38.5 degrees. In the non-drainage group, 55 (94.8%) of the 58 febrile patients were less than 38.5 degrees, and the remaining 3 (5.2%) patients were greater than 38.5 degrees. For a fever rate of less than 38.5 degrees, there was a statistically significant difference between the two groups ($p < 0.05$). However, there was no statistical difference between the two groups when the fever rate was greater than 38.5 degrees ($p > 0.05$).

There was no significant difference in symptomatic epidural hematoma when the two groups were compared. Only one patient with L4/5 disc herniation in the non-drainage group had a recurrence of lower extremity symptoms second days after surgery (Fig. 2). The MRI examination revealed the formation of epidural hematoma, which resulted in nerve compression and recurrence of lower extremity symptoms. The patient's symptoms had been improved by removing the epidural hematoma through revision surgery. There was no difference in the risk of wound infection as a result of none of the 420 patients incurred wound infections.

In the closed drainage group, stump rupture was found in one patient after removal of the drain tube. Then a revision surgery was performed to remove the stump of the drain left inside the patient. Consequently, a total of two patients underwent revision surgery, each of the two groups had one case. The difference in revision operation rate between patients in the closed drainage group (0.5%) and the non-drainage group (0.5%) was not statistically significant ($p > 0.05$). The primary results are listed in Table 2.

Follow-up Results

Follow-up results are presented in Table 3–5. All patients underwent a two-year follow-up period. At preoperative, postoperative, and the last follow-up, there were no significant differences in the lower extremity VAS score and ODI score when the two groups were compared ($p > 0.05$). Similarly, at preoperative, postoperative week 1, week 2, month 1, and the last follow-up, there was also no significant difference in the operation area VAS score when the two groups were compared ($p > 0.05$). Only compared the postoperative day 1 operation area VAS score, the closed drainage group was better than the non-drainage group and with a significant statistical difference ($p < 0.05$).

Discussion

Closed drainage has long been used following extensive spinal surgery [12–14]. In contrast, the use of drain after single-level disc surgery remains controversial [3, 18]. A prospective, randomized clinical study of 50 single-level lumbar disc surgery reported by Mirzai et al [6], indicated that inserting a drain decreased the incidence of hematoma detected by MRI on the first postoperative day, 89% of patients without a drain had hematoma, and only 36% of patients with a drain had hematoma. That means absence of hematoma was increased from 11–64% after using a drain. In our study, due to the limitations of study conditions, we did not undergo postoperative MRI examination to compare the incidence of hematoma in both groups. We studied the occurrence of postoperative fever and symptomatic hematoma in the patients. The fever rate in the drainage group (18.7%) was lower than that in the non-drainage group (28.2%). After statistical analysis, we found the difference in fever rate was mainly due to the difference between the two groups of patients with low fever. It is well known the low fever is often caused by the absorption of hematoma after operation. Therefore, low fever rate may be because the incidence of postoperative hematoma in the drainage group is lower than that in the non-drainage group, and there is less absorption of the hematoma. Symptomatic hematoma occurred in only 1 case of the two groups, and there was no statistically significant difference in the incidence of symptomatic hematoma between the two groups. So, we believe that drainage may be benefit in preventing the formation of hematoma after single-level lumbar discectomy, but we do not think there is any significance for the prevention of symptomatic hematoma.

With the progress of medical technology and the increase of aseptic concept, the infection rate of spine surgery becomes lower and lower [19]. Dimick et al [20] calculated 5036 patients having spinal surgery would need to be enrolled to show a reduction in the infection rate from 2–1%. For single-level lumbar discectomy, this less traumatic surgery, the infection rate is even lower. In 1996, Payne et al [2] randomized 200 single-level lumbar laminectomy patients into two groups based on the presence or absence of a drain, and found 2 of 103 patients (1.9%) with a drain and 1of 97 patients (1.0%) without a drain had wound infections develop. In 2010, Kanayama et al [3] retrospectively reviewed 560 patients underwent single-level lumbar decompression or discectomy, in which 298 cases received drains and the left 262 cases did not. As a result, the infection rate was 0; none of the 560 patients incurred wound infections. The both authors concluded closed drainage provided no benefit with respect to rates of infection. Similar results were achieved in our study, with no infection in either of the two groups.

There was 1 patient undergoing revision surgery in each of the two groups, and there was no significant difference in the re-operation rate. It can be seen that drainage can reduce the postoperative fever, and there is no other reduction of postoperative complications in single-level lumbar decompression patients.

With two years follow-up, only compared the postoperative day 1 operation area VAS score, the closed drainage group of 5.1 ± 0.8 was better than the non-drainage group of 6.0 ± 0.7 and with a significant statistical difference ($p < 0.05$). The other evaluations of operation area VAS score, lower extremity VAS score, and ODI score were not statistically different between the two groups. This shows that the insertion of a drainage tube eliminates the bleeding and exudate of the intraoperative area, and has the effect of relieving pain in the early postoperative period (postoperative day 1), but long-term observation is of no significance for the patients' pain relief and functional recovery.

Although drainage has the advantages of reducing postoperative hematoma formation, reducing postoperative fever, and relieving postoperative pain in the early postoperative period, there are some disadvantages, conversely. It is recognized that drains may provide a conduit for the entry of bacteria. The literature carries conflicting reports on the use of drains [21, 22]. Despite in our study, the drainage group did not appear in infected patients, some drainage systems have been associated with high infection rates [1]. A meta-analysis suggested that drains may do more harm than good, and that their only proven benefit is a reduced need for the change of dressings [23]. Meanwhile, under the current status of promoting day surgery, patients with drainage may not be able to discharge the day after surgery. This is not conducive to improving medical efficiency.

This study had several limitations. First, we narrowed our study group to lumbar discectomy patients with single level. Because of the lower incidence for spinal epidural hematoma when compared to other multilevel lumbar procedures, thus, our findings should be applied only to single-level lumbar discectomy. Second, due to the limitations of study conditions, we have not undergone postoperative MRI examination to compare the incidence of hematoma in both groups. We speculate that the rate of hematoma formation in the drainage group is lower referring to after draining the patients with a lower fever rate. Third, while the follow-up period of 2-year in the present study was comparable to that used in many literature studies, a longer follow-up with regarding epidural fibrosis might enable us to have a better understanding on the long-term effect of using a drain. Fourth, although this study is by far the largest known randomized controlled study in this area, the number of patients in both groups was small, which may limit the generalizability of the results.

Conclusions

With this two-year follow-up, prospective, randomized study, we believe that closed drainage can be beneficial to reduce postoperative fever rate and alleviate postoperative operation area pain in the early postoperative period, but it has no effect on preventing postoperative occurrence of symptomatic epidural hematoma, wound infections, need for revision surgery; and improving clinical outcomes in single-level lumbar discectomy.

Abbreviations

VAS
visual analog scale;
ODI
Oswestry Disability Index;
L
lumbar;
MRI
Magnetic Resonance Imaging.

Declarations

Acknowledgements

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Availability of data and materials

The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

B.W. and D.H. designed the research. H.G. wrote the manuscript. Z.J. analysed the data. X.G. and Y.Z. acquired data. H.G. and L.Y. performed surgical treatment. B.W. supervised the project and reviewed the manuscript.

Ethics approval and consent to participate

This study was approved by the Medical Ethics Committee of Honghui Hospital and informed consent was obtained from all of the individual participants included in the study.

Consent for publication

Written informed consent for publication was obtained from all patients.

Competing interests

The authors declare that they have no competing interests.

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Tables

TABLE 1

Demographic and clinical characteristics of the patients.

	Closed drainage group (n=214)	Non-drainage group (n=206)	*p*
Age (yr.)	50.4 ± 6.6	49.6 ± 6.2	0.220
Male to female ratio	122:92	129:77	-
Operation time (min.)	60.6 ± 4.1	60.2 ± 3.9	0.359
Intraoperative blood loss (ml.)	62.7 ± 6.5	62.6 ± 6.2	0.856
Hemorrhagic collection (ml.)	54.2 ± 15.5	-	-

Data are presented as mean±standard deviation.

TABLE 2

Summary of the primary clinical results.

	Closed drainage group	Non-drainage group	*p*
Fever	40	58	0.022[a]
<38.5°C	38	55	0.027[a]
≥38.5°C	2	3	0.308[b]
SEH	0	1	0.491[b]
Infection	0	0	-
Revision surgery	1	1	0.501[b]

SEH: symptomatic epidural hematomas.

[a] chi square test; [b] Fisher exact test

TABLE 3

Summary of the operation area VAS follow-up results.

	Closed drainage group	Non-drainage group	*p*
Preoperative	2.2 ± 0.8	2.0 ± 0.8	0.143
Day 1	5.1 ± 0.8	6.0 ± 0.7	0.000
Week 1	3.9 ± 0.8	4.0 ± 0.8	0.105
Week 2	2.9 ± 0.9	3.1 ± 0.7	0.127
Month 1	1.3 ± 0.6	1.4 ± 0.7	0.139
Last follow-up	0.8 ± 0.6	0.9 ± 0.6	0.215

Data are presented as mean±standard deviation.

VAS: visual analog scale.

TABLE 4

Summary of the lower extremity VAS follow-up results.

	Closed drainage group	Non-drainage group	*p*
Preoperative	7.6 ± 0.8	7.7 ± 0.7	0.179
Postoperative	2.7 ± 0.7	2.8 ± 0.7	0.134
Last follow-up	2.0 ± 0.7	2.1 ± 0.6	0.128

Data are presented as mean±standard deviation.

VAS: visual analog scale.

TABLE 5

Summary of the Oswestry Disability Index follow-up results.

	Closed drainage group	Non-drainage group	*p*
Preoperative	59.9 ± 4.1	59.8 ± 4.2	0.736
Postoperative	32.4 ± 4.0	32.8 ± 3.9	0.348
Last follow-up	22.5 ± 3.1	22.8 ± 2.7	0.298

Data are presented as mean±standard deviation.

Figures

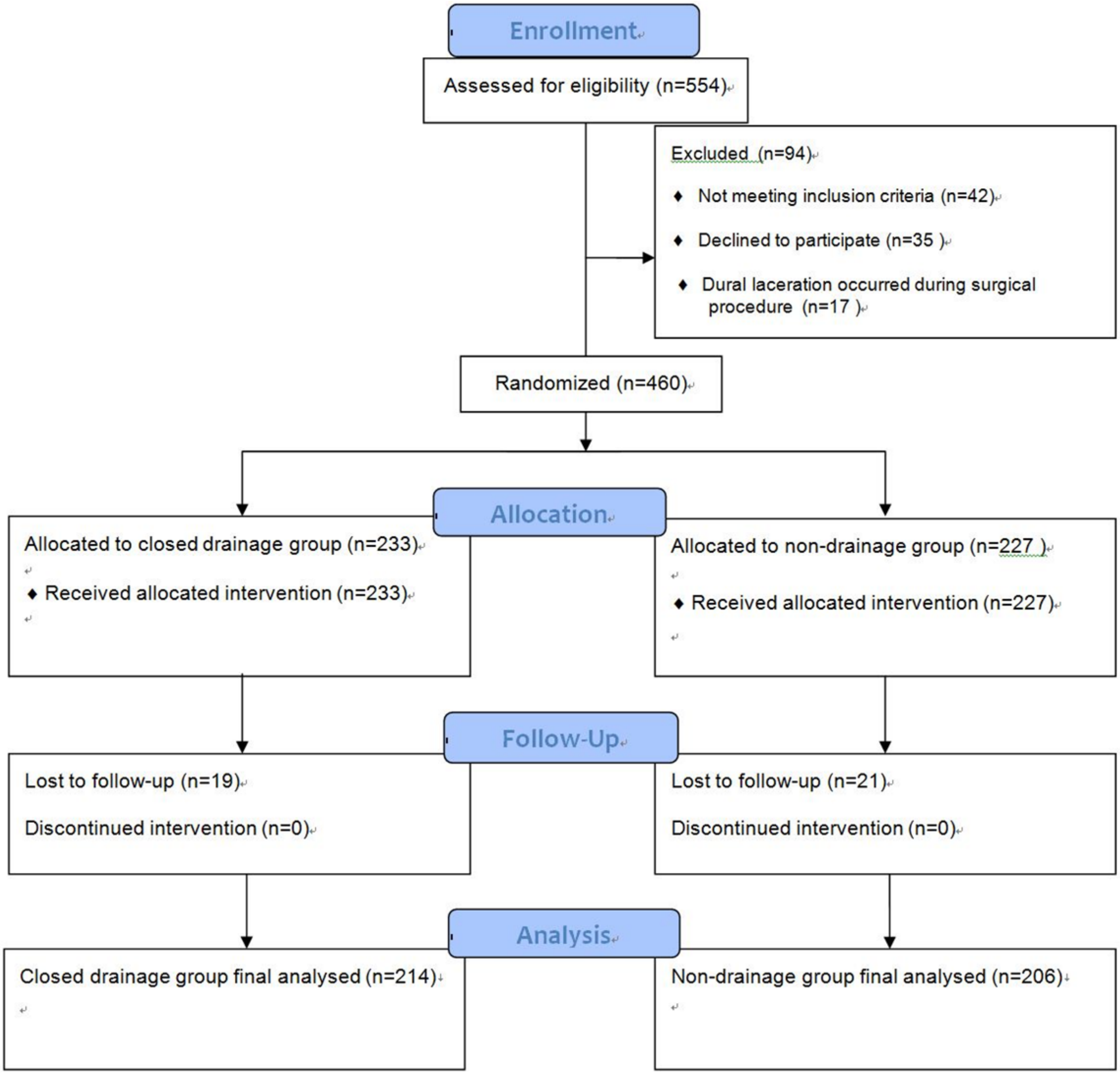

Figure 1

The flowchart. A drawing of the elements of the study design.

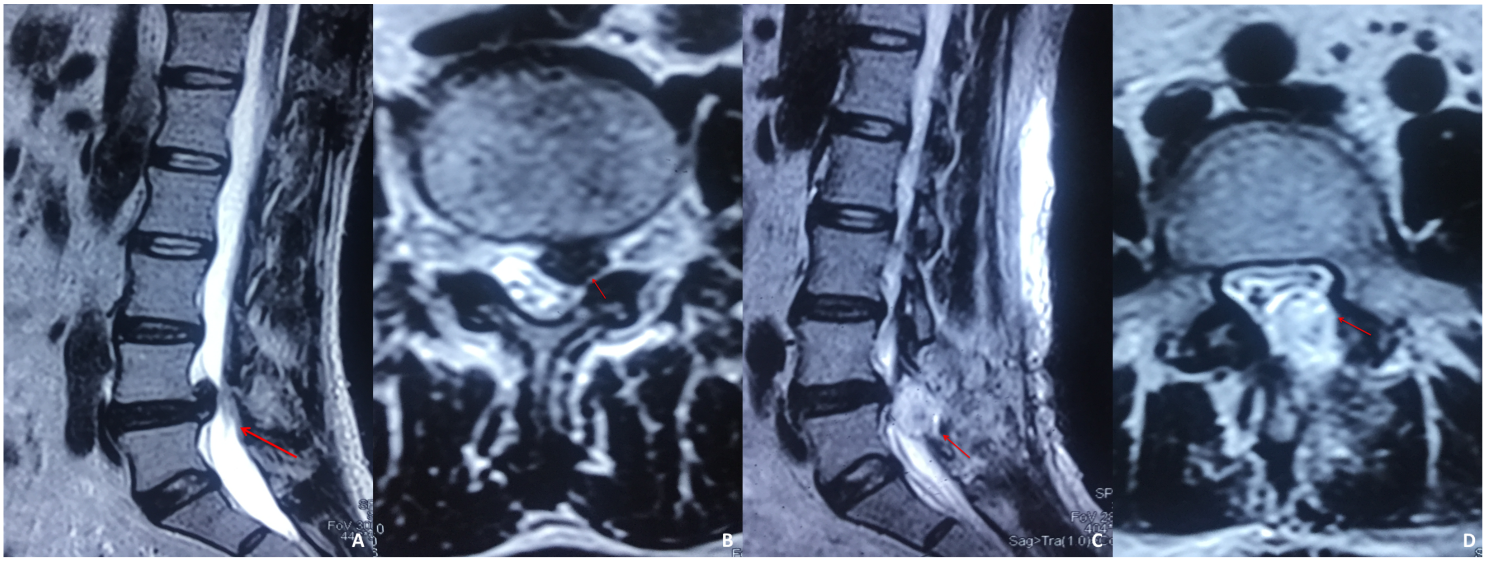

Figure 2

The only one patient with symptomatic epidural hematoma. A 37-year-old male with a disc herniation at L4/5 segment required a discectomy treatment. (A) Sagittal MRI showed L4/5 segment with huge disc herniation. (B) Transverse MRI showed herniated nucleus pulposus tissue, resulting in compression of the left nerve root. (C D) The symptoms of left lower limb pain recurred after discectomy. The sagittal and transverse sections of MRI showed hematoma formation, and the dural sac and left nerve root were compressed obviously.

Supplementary Files

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- patientdata.xlsx