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Clinical Study

Wound drain in lumbar arthrodesis for degenerative disease: an experimental, multicenter, randomized controlled trial

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Abstract

INTRODUCTION: Drains for surgical wound management are frequently used in spine surgery. They are often used to decrease the incidence of postoperative hematoma and decrease wound tension. No conclusive evidence in the literature supports using drains to avoid complications in degenerative lumbar spine surgery.

PURPOSE: We aimed to evaluate wound drains in patients with lumbar arthrodesis for degenerative disorders based on clinical outcomes, complications, hematocrit, and length of stay.

STUDY DESIGN: A multicenter randomized prospective controlled clinical trial.

PATIENT SAMPLE: We enrolled surgical candidates for posterior lumbar decompression and fusion surgery for degenerative disorders from October 2019 to August 2021. Patients were randomized into the drain or nondrain group at nine hospitals. The inclusion criteria were as follows: patients aged 40 to 80 years with lumbar and radicular pain, lumbar degenerative disorder, and primary surgery up to three levels. The exclusion criteria were bleeding abnormalities, bleeding >2,500 mL and dural tears.

OUTCOME MEASURES: Preoperative data including Oswestry disability index (ODI), SF-36, lumbar and lower extremity visual analog scale (VAS), body mass index (BMI), hematocrit, and temperature were recorded. Surgical parameters, including surgical time, complications, estimated blood loss (EBL), postoperative temperature and hematocrit (days 1 and 4), dressing saturation, and length of hospital stay (LOS), were registered.

METHODS: The two groups were assessed preoperatively, perioperatively and at the 1-month follow-up. A REDCap database was used for registration. Data analysis was performed using classical statistics.

RESULTS: One hundred one patients were enrolled using the Redcap database, and 93 patients were evaluated at the final follow-up. Forty-five patients were randomized to the drain group, and 48 were randomized to the nondrain group. The preoperative characteristics were equivalent in both groups: demographic aspects, pain, ODI, SF-36, BMI, hematocrit, and spine pathology. Surgical time, EBL and complications were similar, with no difference between the groups. No

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difference was found between BMI and complications. No difference was observed in dressing saturation or postoperative temperature between the groups. The postoperative day 4 hematocrit was higher in the nondrain group [36.4% (32−39)] than in the drain group [34% (29.7−37.6)] without statistically differences (p=.054). The LOS was higher in the drain group [4 (3−5) days] than in the nondrain group [3 (2−4) days] (p=.007). The quality-of-life score, SF-36, was higher in the nondrain group [67.9 (53.6−79.2)] than in the drain group [56.7 (49.1−66)] (p=.043).

CONCLUSIONS: Nondrain patients presented shorter LOS and better outcomes, with similar complication rates. No difference was found between BMI and complications. Based on this study, in patients undergoing primary posterior spinal decompression and fusion up to three levels for degenerative lumbar disorders, we do not recommend the use of postoperative drains.

Keywords: Arthrodesis; Clinical trial; Drain; Lumbar region; Multicenter trial; Randomized; Spinal fusion

Introduction

Preventing complications in spinal surgery is a critical concern. Surgical wound hematomas are a complication that occurs in 0.2% to 2.9% of patients and may occasionally require revision surgery [1,2]. Hematomas can be asymptomatic or symptomatic when associated with increased wound tension, delayed healing, wound infection, epidural location, and spinal cord or nerve root compression.

Drains for surgical wound management are frequently used in spinal surgery to decrease the incidence of postoperative hematoma. However, their use has been associated with disadvantages such as retrograde infection, increased loss of postoperative blood with consequent anemia requiring transfusion [3], skin and deep tissue inflammation [4], an increased length of stay (LOS), and increased hospital costs [5].

Abundant literature has described the benefits of surgical drains [1−17]. Muthu published a systematic review that analyzed the evidence regarding drain usage [18]. Most of the studies included different pathologies, spine segments, and techniques. However, no evidence-based conclusions were reported because of the heterogeneity of the groups. In particular, no conclusive evidence supports using drains to prevent complications in lumbar degenerative spine surgery.

This study aimed to determine the benefit and safety of using postoperative drains in posterior lumbar arthrodesis for degenerative pathology.

Methods

Trial design

We performed a multicenter, prospective, randomized, controlled, open-label clinical trial in patients with degenerative lumbar spine pathology (spondylolisthesis, spinal stenosis, discogenic pain disorder, and recurrent disc herniation). Ethics committee approval was obtained from each hospital, and each patient provided informed consent.

The study was performed at nine hospitals in Santiago, Chile with recruitment taking place from October 2019 to August 2021. Each center had a designated surgeon in charge of the follow-up and data registration. A weekly meeting was used for coordination.

Sample calculations

Due to lack of standard deviation measurements, we searched the best available evidence which corresponds to the study made by Brown and Brookfield 2004 [8] study, with the same design as our study, a randomized controlled clinical trial, where 83 patients were analyzed. We copied this number with a 20% increase considering the risk of patient loss, so that the results do not lose the 80% of statistical power, obtaining a total sample size of 101 subjects.

Patient sample

All the recruited patients had lumbar and radicular pain due to degenerative lumbar disorders, resulting in conservative treatment failure. Medical records, plain radiographs, and magnetic resonance imaging (MRI) studies were previously obtained.

Inclusion/exclusion criteria

The inclusion criteria were: patients aged between 40 and 80 years undergoing lumbar posterior decompression and instrumented fusion with pedicle screws; fusion was performed from one to three levels using an open technique, with or without PLIF (posterior lumbar interbody fusion) or TLIF (transforaminal lumbar interbody fusion). The exclusion criteria were previous spine surgery, minimally invasive surgery, intraoperative bleeding over 2,500 mL, coagulopathies, dural tears, and the use of bone morphogenetic protein-2. The inclusion and exclusion criteria are described within the study flowchart (Flowchart).

Surgical procedure

All the patients had undergone posterior-only lumbar decompression with full laminectomy and fusion with

pedicle screw system through an open technique using magnification glasses. The patients were randomized 1 hour before surgery using the REDCap application (Vanderbilt University v11.0.3) into the group with or without drains. Hemosuc 400 plus (Inmed, Chile) drainage was used. According to the prior random assignment, a suction drain was placed in the drain group at a subfascial location (deep, under the lumbar fascia) at the end of the surgery. No superficial drains were used. Surgical wound closure was performed in several layers, including the muscular layer, fascia, and subcutaneous tissue in one or two layers depending on the thickness of the adipose pad, followed by intradermal suture.

Outcome measures

We defined length of stay (LOS) as primary outcome due to consistent evidence that supported the biggest measurement differences in this outcome [5,10,18]. As secondary outcomes we measured: postoperative hematocrit, postoperative parameters (surgical parameters and dressing characteristics), postoperative temperature, BMI, preoperative clinical outcomes (VAS, ODI, SF-36), clinical outcomes 30 days after surgery and complications (Figure).

Preoperative data including Oswestry disability index (ODI), SF-36, lumbar and lower extremity visual analog scale (VAS) were recorded. Intraoperative metrics such as surgical time, complications, estimated blood loss (EBL) were included. Postoperative: ODI, SF-36, lumbar and lower extremity (VAS) 1 month after surgery were evaluated.

Patient-reported clinical outcomes were evaluated preoperatively and 1 month after surgery using validated questionnaires. Low back and radicular pain were assessed using a visual analog scale (VAS) ranging from 0 (no pain) to 10 (worst pain imaginable). Functional impact was measured using the ODI. Health status and quality of life were measured using SF-36 questionnaires.

The patient's weight, height, and body mass index (BMI) were registered. Each patient had a preoperative hematocrit registration.

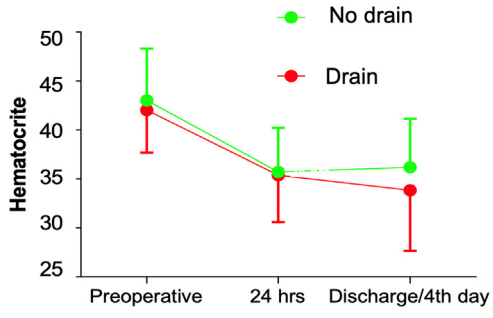


Figure. Hematocrit variation for drain and nondrain group during the follow-up period. Red dots indicate drain group; green dots indicate nondrain group. Error bars 95% confidence intervals.

Primary and secondary diagnoses were registered to compare the complexity of the surgery.

We also recorded surgical parameters, including; surgical time, number of instrumented levels, additional use of transforaminal lumbar interbody fusion (TLIF) or posterior lumbar interbody fusion (PLIF), and estimated blood loss (EBL).

The postoperative dressing characteristics were assessed by a trained spine surgeon and was graded from 1 to 5 based on local classification (Table 1).

The daily exudate volume through the drain and number of days were measured until the drain was removed. The postoperative temperature after surgery was recorded up to discharge.

Postoperative day one (24 hours postoperatively) and discharge or the fourth postoperative day hematocrit was measured for each patient to evaluate the blood drain impact.

The postoperative blood or red cell transfusion requirement was recorded. All medical, neurological, and surgical complication during the first month after surgery was registered.

Finally, the length of stay (LOS), readmission, or the need for revision surgery during the first month after surgery was recorded.

Statistical analysis

All the information was recorded in the REDCap database (Vanderbilt University v11.0.3).

Statistical analysis was performed using classical statistics.

Categorical variables were described as frequencies and percentages. Histograms and the Shapiro-Wilk test were used to evaluate the distribution of numerical variables that were not distributed normally; therefore, the median and interquartile range (IQR) were used (Appendix). To compare the outcomes between the drain and nondrain groups,

Table 1
Grading of dressing characteristics based on local classification in postoperated patients

Grade	Description	Drain group	Nondrain group
I	Dry	30	41
II	Blood drain occupying an area less than one third of the dressing	14	5
III	Blood drain occupying an area between 1/3 and 2/3 of the dressing	1	0
IV	Blood drain occupying an area greater than 2/3 and up to the entire dressing with blood	0	0
V	Entire dressing soaked with blood, sheets with blood	1	1

Chi-square test: p value =.10.

Table 2
Comparison of baseline characteristics between patients with and without drain

	Drain group (n=45)	Nondrain group (n=48)	p value
Age median (range)	56 (49−66)	59 (50−67)	.543
Sex, n (%)			.678
Female	26 (51%)	25 (49%)	
Male	19 (45.2%)	23 (54.8%)	
Height (meter)	1.62 (1.58−1.71)	1.65 (1.57−1.75)	.839
Body weight (kg)	73 (65−80)	76.4 (66−86)	.378
BMI (kg/m^2)	32.5 (26.6−38.2)	35.9 (26.8−42)	.229
Preoperative diagnoses (n, %)			.908
Lumbar stenosis	25 (54.3%)	23 (48.9%)	
Spondylolisthesis	12 (26%)	16 (34%)	
Herniated disc	2 (4.4%)	3 (6.5%)	
Other	7 (15.3%)	5 (10.6%)	
Preoperative hematocrit (%)	43.1 (38.9−46)	42.9 (40−47.5)	.636
Preoperative lumbar VAS	7 (6−10)	8 (6−9)	.679
Preoperative lower extremity VAS	8 (6−9)	8 (5−9)	.904
Preoperative ODI	56 (40−68)	52 (40−60)	.252
Preoperative SF-36	26.6 (19.1−42.7)	35.5 (25−48)	.024

BMI, body mass index; VAS, visual analog scale; ODI, Oswestry disability index; SF-36, 36-Item short form health survey. Continues: median (IQR). To compare Mann-Whitney test was used. Categorical variables: frequency (percentage). To compare chi-square test was used. Statistical significance at the p<.05 level.

chi-squared and the Mann-Whitney test were used. A p value <.05 was considered statistically significant. The statistical software Stata 14 Texas Corp. LLC was used.

Results

Patient population

A total of 101 patients were enrolled, with 93 patients present at the final follow-up. Forty-five patients were randomized to the drain group, and forty-eight were randomized to the nondrain group (see Flowchart).

From the 93 patients, 51 (54.8%) were female and 42 (45.2%) were male. In the drain group were 26 (57.8%) female and 19 (42.2%) and the nondrain group 25 (52%) female and 23 (48%) males. No differences were found p=.678.

The median age in the total sample was 57 years (49−66). In the drain group the median age was 56 years (49−66) and in the nondrain group was 59 years (50−67), p=.543. The preoperative lumbar VAS was 7 in the drain group and 8 in the nondrain group (p=.679). The preoperative radicular VAS was 8 in both groups (p=.904). The baseline ODI was 56 in drain group and 52 in the nondrain group (p=.252). The baseline SF-36 score was 26.6 in the drain group and 35.5 in the nondrain group (p=.024). No difference was found in the BMI between the drain group (32.5 kg/m^2; 26.6−38.2) and nondrain group (35.9 kg/m^2; 26.8−42) (p=.229). The median preoperative hematocrit was 43% (p=.636). The preoperative demographics and baseline characteristics were similar between the drain and nondrain groups. Likewise, the primary and secondary diagnoses were similar in both groups. Lumbar spinal stenosis was the most frequent primary diagnosis, 54.3% in drain group and 48.9% in nondrain group (p=.908). The baseline characteristics are shown in detail in Table 2.

Primary outcomes

Length of stay

Patients in the nondrain group stayed 3 (2−4) days compared with 4 (3−5) days in the drain group (p=.007). No patient was readmitted to the hospital during the first 30 days after surgery.

Secondary outcomes

Postoperative hematocrit

We did not observe a different hematocrit at first day between the groups (p=.412). There was no statistical significance in hematocrit between the drain group (34%; IQR: 29.7%−37.6%) and the nondrain group (36.4%; IQR: 33.2%−39%), at discharge or on the fourth day (p=.054) (Table 3). No difference was found in blood transfusion rates.

Postoperative parameters

Surgical parameters: The surgical time was similar in both groups, 180 minutes in drain group and 151 minutes in nondrain group (p=.468). The number of operated levels was similar, with a median of two levels instrumented in both groups, with L2 as the proximal level. TLIF and PLIF were performed in 20.4% of the cases without a difference between the groups. The EBL during surgery was 400 milliliters (mL) in the drain group and 350 mL in the nondrain group (p=.170).

Table 3
Outcomes for drain and nondrain group after surgery for 30 days follow-up

	Drain Group (n=45)	Nondrain Group (n=48)	p value
Postoperative lumbar VAS	3 (1–5)	3 (1–4)	.553
Postoperative lower extremity VAS	1 (0–5)	1 (0–4)	.554
Postoperative ODI	26.7 (16–48.9)	22.2 (15.6–36)	.249
Postoperative SF-36	56.7 (49.1–66)	67.9 (53.6–79.2)	**.043**
Hematocrit			
24 h post-op	34.2 (31.6–39.3)	36 (32–39)	.412
Discharge/4th day postop	34 (29.7–37.6)	36.4 (32–39)	**.054**
Surgery-related outcomes			
Operative time (min)	180 (150–202)	151 (140–210)	.468
Estimated blood loss (mL)	400 (250–500)	350 (200–400)	.170
Length of hospital stay (days)	4 (3–5)	3 (2–4)	**.007**
Post-op peak temperature (°C)	36.7 (36.5–36.9)	36.8 (36.7–37)	.148
Surgical complication	5 (11.1%)	2 (4.5%)	.250
Dressing characteristics			
Grade			.101
I	30	41	
II	14	5	
III	1	0	
IV	0	0	
V	1	1	

VAS, visual analog scale; ODI, Oswestry disability index; SF-36, 36-Item short form health survey. Continuous variables: median (IQR). To compare Mann-Whitney test was used. Categorical variables: Frequency (%). To compare chi-square test was used. Statistical significance at the p< .05 level.

Bold values denote statistical significance p<.05.

Drain output: In drain group, the mean output through the drain was 370 mL, with an average of 2.61 days before removal.

Dressing characteristics: Based on our classification, no difference was found between the drain and nondrain groups using chi-squared test (p=.101) (Table 3).

Postoperative temperature

The temperature was assessed every day up to discharge, and the maximum temperature in the drain group was 36.7°C and 36.8°C in the nondrain group (p=.148). In both groups, the median highest temperature was recorded on the first postoperative day. Similar to the other numerical variables, the postoperative axillary temperature did not have a normal distribution, as shown in Graphic 1.

BMI and clinical outcomes

No differences were found in the clinical results of the SF-36 and ODI scores between the patients with normal weight (Nw; BMI <25 kg/m^2) and those with overweight or obesity (Ow-Ob; BMI ≥25 kg/m^2). In the Ow-Ob group, the postoperative SF36 score was 60.5 (51.4–72.5), and Nw was 69.6 (45.3–83.8) (p=.198). The postoperative ODI score of the Ow-Ob group was 24 (16–45) and that of the Nw group was 25 (12–30) (p=.836).

Clinical outcomes 30 days after surgery

Lumbar and radicular pain improved after surgery in both groups, without a difference between them. Lumbar pain based on VAS was identical between the drain and nondrain groups [3 (1–5) and 3 (1–4), respectively; p=.553]. The lower extremity VAS was 1.0 (0–5) in the drain group and 1.0 (0–4) in the nondrain group (p=.554). The ODI was 26.1 in drain group and 22.2 in the nondrain group (p=.249). Regarding quality of life in SF-36, the drain group score was 56.7 and in the nondrain group 67.9 (p=.043), favoring a better quality of life in the nondrain group.

Complications

The perioperative complications similar between the groups, with five patients presenting complications in the drain group (11.1%) and two in the nondrain group (4.5%) (p=.250). These included radiculitis, pulmonary embolism, screw malposition, ulnar nerve neuropraxia (from improper positioning during surgery) and deep wound infection in the drain group; and radiculitis and superficial seroma in the nondrain group. Re-operation rate was 2.2%, both patients from the drain group. Regarding BMI patients were classified as of normal weight, overweight, and obese patients and were evenly distributed between the study groups. No difference in complications was associated to BMI.

Discussion

Drain usage following spinal surgery is common. Theoretically, its use could prevent wound and epidural hematoma formation, surgical site infection and wound breakdown. However, the indication continues to be controversial [1,2,8,11,19-25].

Our prospective, multicenter, randomized and controlled trial included 93 patients with lumbar spine degenerative pathology undergoing decompression and fusion up to three levels. To our best knowledge, this is the first multicenter RCT to be performed in the Latin American population, which may shed some light on the controversies in using deep drain in degenerative spinal surgery.

Unlike other studies that used drain in spinal surgery, our inclusion and exclusion criteria were strict. We considered only patients with low back and radicular pain secondary to degenerative lumbar pathologies undergoing posterior decompression and fusion surgery up to three levels without prior lumbar surgery. Thus, we formed a homogeneous group. Patients with these characteristics who have undergone this type of surgery are one of the most frequent indications for surgery performed by a spinal surgeon.

There is some evidence available that supports the use of drains in spine surgery. The study developed by Blank et al. [13] included 30 patients, 18 with drains and 12 without drains, who had undergone scoliosis surgery. While none of the patients in the drain group presented complications, three of the twelve patients in the nondrain group developed wound complications. No statistical analysis was performed, but they concluded that using postoperative drain improves immediate postoperative wound care without increasing blood loss and the need for blood transfusion in patients operated on for adolescent idiopathic scoliosis (AIS). Guo et al. conducted an RCT comparing drain and no drain in 420 patients undergoing lumbar micro-discectomy, in their study they report higher temperature (p=.027) and higher pain in the nondrain group on day 1 after surgery (VAS 5.1 ± 0.8 vs 6.0 ± 0.7, p=0.00), with no difference in other complications, pain and clinical outcomes [2]. We did not find a statistically difference in complications in our study between drain group (11.1%) and nondrain group (4.5%) with p=.25.

Furthermore, reports have favored using postoperative subfascial drains to prevent hematoma formation. Mirzai et al. published an RCT of 50 patients undergoing lumbar disc herniation surgery. They measured epidural hematoma formation using MRI and found that 89% of patients in the group without drain had asymptomatic epidural hematoma on the first postoperative day vs 36% in the group with drain (p=.000). Nevertheless, the patients remained asymptomatic and without statistically differences regarding pain and the long-term functional status (p=.4) [21]. Our study did not directly evaluate the formation of epidural hematoma; however, no neurological deficit attributable to this complication was observed.

In contrast, some studies have questioned the benefit of using drains in spinal surgery. Brown and Brookfield developed an RCT including 83 patients, 42 with drains and 41 without drains, who received single-level spinal surgery (lumbar disc herniation, spinal stenosis, and degenerative spondylolisthesis). They reported no complications in either group, with the only difference being a higher temperature in patients in the "no-drain" group during the first postoperative day without adverse effects on the outcome [8]. The RCT by Ovadia et al. studied the use of subfascial drain in AIS population. They included 100 patients operated on to correct deformity, 48 in drain group and 53 in nondrain group. They found only a higher temperature in the nondrain group on day 6 after surgery (p=.017) with no difference in blood loss, transfusion and infection rate [24]. Brazolino et al. published an RCT including 60 patients operated on for single-level degenerative spinal stenosis with decompression and fusion, 30 in each randomized group, finding no difference at last follow-up (28 days) [23]. Similarly, Payne et al. conducted an RCT including 200 patients with single-level lumbar spinal stenosis operated with decompression but without fusion. They reported no difference in infection rate and clinical outcomes [20].

Evidence exists associating drain with complications, such as an increased risk of retrograde infection. In this regard, Takemoto et al. compared three groups: patients with antibiotics for 24 hours after drain insertion (156 patients), patients with antibiotics for the entire duration that the drain remained inside the patient (167 patients) and patients without a drain (129 patients). The work concluded that the risk of operative wound infection increases with the permanence of the drain for more than 3 days independent of antibiotic therapy (8.3% vs 23.8%, p=.03) [26]. Our patients presented a lower rate of postoperative infection than that reported in the work just mentioned, with one case of deep infection in the drain group and one superficial infection in the nondrain group at the end of the follow-up, we do not attribute the infection to the use or absence of a drain since no differences were found between the groups (p=.25).

The use of a drain has been associated with greater blood, transfusion requirements and a longer length of stay (LOS). Walid et al. performed a retrospective study of 402 patients who received lumbar decompression and fusion for degenerative lumbar pathology. Posthemorrhagic anemia was statistically more common in the group with drains (23.5% vs 7.7%; p=.000). Allogenic blood transfusion was also statistically more common in the drained group (23.9% vs 6.8%; p=.000) [16]. Likewise, Adogwa et al. reviewed the data of 321 patients comparing the use and nonuse of subfascial drain in cervical canal stenosis. The drain group required 14 times more transfusions and a hospital stay two times longer than the nondrain group [10]. Another study published by Adogwa et al. in the same journal compared the use and nonuse of drain in a retrospective cohort of 139 patients operated with decompression and fusion in spinal deformities. In the nondrain group, no postoperative infections were recorded compared with the drain group, in which 2.6% had either superficial (1.7%) or deep (0.9%) infection. A statistically difference was found in the length of stay, which was longer in the drain group (5.0 days) than in the nondrain group (2.8 days) (p<.0001) [5]. In our study we found a higher hematocrit on the fourth postoperative day in the nondrain group (36.4 vs 34%; p=.054), however, we could not identify a statistically difference. Perhaps by narrowing our inclusion criteria to surgery up to three levels, the operative time, intraoperative bleeding and complexity of the surgery were lower than those of Adogwa et al. and Walid et al. [5,10,16]. This could explain why we didn't find a higher blood loss in our drain group. On the other hand, we confirmed previous reports of a longer LOS using drain in our study (4 vs 3 days; p=.007).

To our best knowledge, the most recent RCT in the literature, comparable to our study, was developed by Gubin et al. [25] (N=155, 80 with drains and 75 without drains). The primary outcome was total perioperative blood loss, which was higher in the "drain" group (716 ± 312.97 mL vs 377.9 ± 295.72 mL; p<.0001). The authors concluded that not using drains after multilevel posterior spinal

Table 4
Characteristics of RCT studies reviewed and cited in this article

Author	Year	Sample size	Population	Study group		Diagnosis	Surgery type	Primary outcome	Follow-up	Significant findings
				Drain	No drain					
Payne et al. [20]	1996	200	Age: NR % Male: NR	103	97	Single-level degenerative lumbar stenosis	Decompression without fusion	Complications	14 days	No difference
Brown et al. [8]	2004	83	Age: 67.4 years % Male: NR	42	41	Degenerative lumbar stenosis	Decompression and fusion	Complications	1 year	Higher temperature in no drain group on day 1 after surgery (p=.0437)
Mirzai et al. [21]	2006	50	Age: 47 years % Male: 72.7	22	28	Lumbar disc herniation	Open microdiscectomy	Postoperative epidural hematoma	6 months	Higher postoperative epidural hematoma in no drain group (89 vs 36%, p=.00) Higher epidural fibrosis in no drain group on 6-month follow-up (58.3 vs 31.6%, p=.08)
Hung et al. [22]	2017	56	Age: 63.2 years % Male: 35.7	28	28	Grade 1 spondylolisthesis, degenerative disk disease	MIS TLIF one or two levels	NR	25.3 months	No drain group started ambulation 1 day earlier (p<.001)
Brazolino et al. [23]	2017	60	Age: 53.3 years % Male: NR	30	30	Degenerative lumbar stenosis	Decompression and fusion	Complications	28 days	No difference
Ovadia et al. [24]	2019	100	Age: 15.7 years % Male: 73	48	52	Adolescent idiopathic scoliosis	Deformity correction	Complications	20 months	Higher temperature in no drain group on day 6 after surgery (p=.017)
Gubin et al. [25]	2019	155	Age: 48.4 years % Male: 41.2	80	75	Degenerative, trauma and tumor	Multilevel posterior spinal surgery	Perioperative blood loss	6 months	Higher total perioperative blood loss in drain group (716 ± 312.97 mL vs 377.9 ± 295.72 mL, p<.0001) Higher transfusion volume in drain group (285 ± 81.76 vs 3.1 ± 0 mL per patient, p=.027) Higher number of aspirations in no drain group (87 vs 42, p=.0004)
Guo et al. [2]	2020	420	Age: 50 years % Male: 59.7	214	206	Lumbar disc herniation	Open microdiscectomy	Complications	2 years	Higher temperature in no drain group after surgery (p=.027) Higher pain in No Drain group on day 1 after surgery (VAS 5.1 ± 0.8 vs 6.0 ± 0.7, p=.00)

NR, not reported; VAS, visual analog scale; ODI, Oswestry disability index; SF-36, 36-Item short form health survey. Statistical significance at the p<.05 level.

surgery reduces postoperative blood loss and transfusion requirements. However, they included patients undergoing posterior spinal surgery for many different diagnoses (trauma, spinal canal stenosis, spondylolisthesis, deformity and tumor) [25]. Our study used stricter inclusion criteria (decompression and fusion in degenerative spine) and revealed no statistically differences in the estimated blood loss.

The evidence from systematic reviews and meta-analyses concludes, in a fairly consensual manner, that no statistically differences were observed between the use or nonuse of drain in patients undergoing decompression and posterior lumbar fusion regarding complications, hematoma, infection and perioperative bleeding [1,3,12,18,27-29]. The meta-analysis by Davidoff et al. [27] included 8 studies, 3 RCTs and 5 non-RCTs (n=1,904; 1,133 patients with drain and 771 patients without drain). They found no difference in SSI, hematoma, neurological injury, or blood loss between the groups. The only difference was that dressings were severely moistened with blood in the group without drain (p=.002). The author concluded that the current available evidence is of limited quality and that RCTs with better experimental designs and a larger number of patients are needed [27]. In the systematic review by Glennie et al., which included 7 studies (2 RCTs), the use of drains did not influence the healing rates and had no effect on infection (OR: 1.33; 95% CI: 0.76−2.30); they could not establish whether surgical drains prevent hematomas causing neurologic compromise because of the high risk of bias in the available studies.[29]

We believe the systematic review and meta-analysis by Muthu et al. presents high- quality evidence one of the strongest lines of supporting evidence in the literature. They included twenty-three studies (9 RCTs, 4 prospective studies, 10 retrospective studies) and summarized the evidence of the risk-benefit analysis of wound drain usage in different spine surgery scenarios (cervical and thoracolumbar degenerative pathology, deformity, trauma and tumor). In single-level lumbar spine surgery, they found evidence that drain usage did not reduce the risk of surgical site infection, neurological deterioration and reoperation rates and moderate-quality evidence that wound drains do not increase the total blood loss but might increase the length of hospital stay. In multilevel thoracolumbar spine surgery, the use of drains did not reduce the risk of surgical site infection and did not provide additional benefit to the patient despite increasing the total blood loss [18]. These findings are in line with ours.

After reviewing the clinical outcomes 30 days after surgery, although no differences were found in pain (VAS) or functionality (ODI), a better quality of life (SF-36) was found in the group without drain in our study (67.9 vs 56.7; p=.044). These results suggest a benefit in clinical outcomes with the nonuse of closed suction drains in posterior spinal fusion surgery for degenerative conditions up to three levels at short-term follow-up (30 days). Whether these results are maintained in the mid- and long-term follow-up is yet to be confirmed. A summary of the RCTs we mention previously can be found in Table 4.

Finally, we believe that drains still have room in spine surgery. As deduced from our exclusion criteria, we still use drains when there is a high risk of symptomatic postoperative epidural hematoma: severe intraoperative bleeding, coagulopathy, more than three-level surgery especially when osteotomy is performed (Schwab 3 or higher) [30] and revision surgeries.

This study has some limitations. We didn't measure hemoglobin changes like some of the other RCTs available did. Also, there was limited data regarding postoperative blood loss measurements in the nondrain group (for instance weighing the dressings might have been useful), these factors could have had an impact on the analysis of differences in EBL between groups. Our study has a relatively short follow-up (30 days). As discussed before, some of the differences found between groups may vary in a longer follow-up. Finally, a cost analysis was not performed. This could have been useful in providing more information to our work.

Our study, methodologically, corresponds a level I evidence and a grade A recommendation. To our best knowledge, this study is the first to conclude that the absence of drain correlates with QoL outcomes (SF-36 scores).

Conclusions

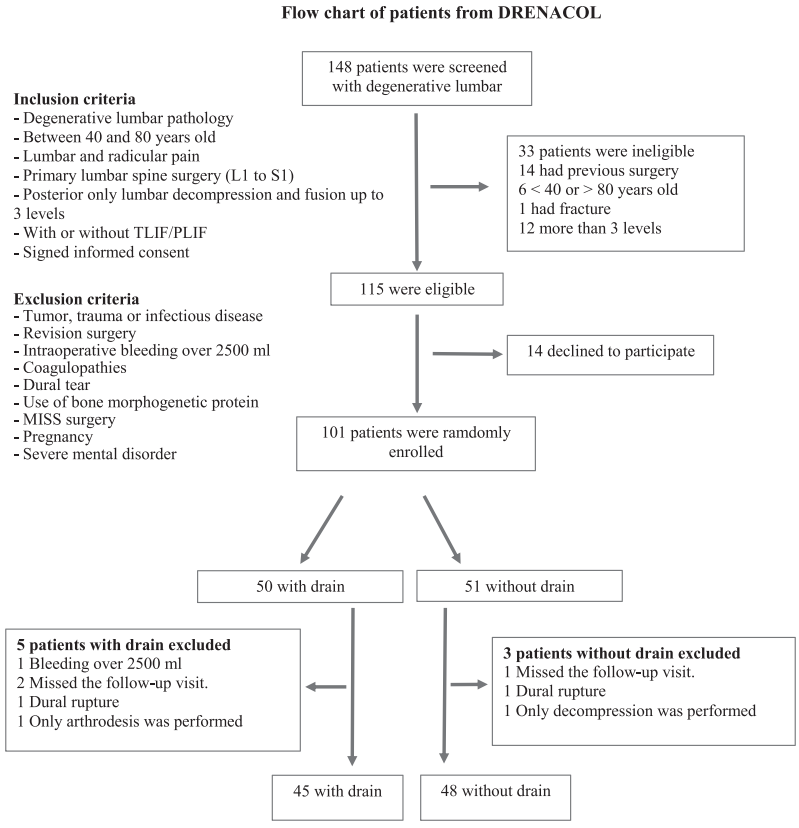
Our RCT showed no advantage in the use of drains regarding complication rate. The absence of a drain resulted in shorter LOS in patients undergoing primary posterior decompression and fusion for degenerative lumbar disorders.

No differences were found in the clinical results of the SF36, ODI scores and complications between the patients with normal weight and those with overweight or obesity in both groups.

Hematocrit at discharge was lower in the drain group without clinical impact.

We did not find advantages in using drains in these patients, with some clinical evidence that the QOL may be better and shorter LOS.

Based on this study, in patients undergoing primary posterior spinal decompression and fusion for degenerative lumbar disorders up to three levels, we do not recommend the use of postoperative drains.



MISS Surgery: Minimal Invasive Spine Surgery technique

Flow chart of patients from DRENACOL
148 patients were screened with degenerative lumbar
Inclusion criteria
- Degenerative lumbar pathology
- Between 40 and 80 years old
- Lumbar and radicular pain
- Primary lumbar spine surgery (L1 to S1)
- Posterior only lumbar decompression and fusion up to 3 levels
- With or without TLIF/PLIF
- Signed informed consent
33 patients were ineligible
14 had previous surgery
6 < 40 or > 80 years old
1 had fracture
12 more than 3 levels
115 were eligible
Exclusion criteria
- Tumor, trauma or infectious disease
- Revision surgery
- Intraoperative bleeding over 2500 ml
- Coagulopathies
- Dural tear
- Use of bone morphogenetic protein
- MISS surgery
- Pregnancy
- Severe mental disorder
14 declined to participate
101 patients were ramdomly enrolled
50 with drain
51 without drain
5 patients with drain excluded
1 Bleeding over 2500 ml
2 Missed the follow-up visit.
1 Dural rupture
1 Only arthrodesis was performed
3 patients without drain excluded
1 Missed the follow-up visit.
1 Dural rupture
1 Only decompression was performed
45 with drain
48 without drain

MISS Surgery: Minimal Invasive Spine Surgery technique

Declarations of Competing Interests

One or more of the authors declare financial or professional relationships on ICMJE-TSJ disclosure forms.

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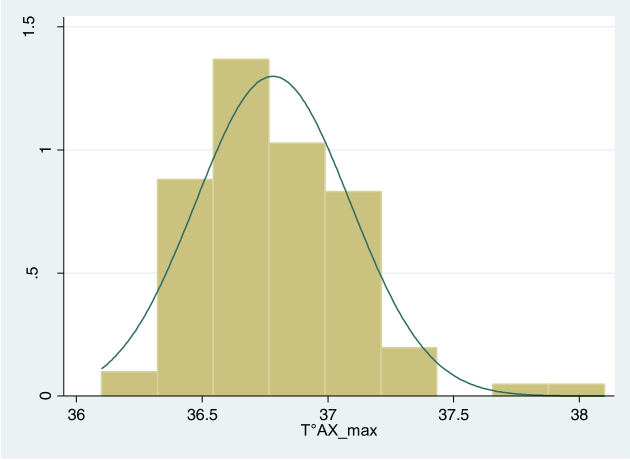
Appendix

Histogram and Shapiro-Wilk test (p=.00008).



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