

Improved Intermittent-clamped Drainage in Lower Lumbar Internal Fixation: A Randomized Prospective Study

Qing-Ying Hao¹, Chu-Yin Liu², Chan-Juan Fu¹, Xiao-Hua Zhang¹, Ming-Sheng Tan¹

¹Department of Spinal Surgery, China-Japan Friendship Hospital, Beijing 100029, China

²Graduate School, Beijing University of Chinese Medicine, Beijing 100029, China

Qing-Ying Hao and Chu-Yin Liu contributed equally to this work.

Abstract

Background: Continuous negative pressure drainage (CNPD) is widely used after lower lumbar internal fixation; however, it may cause tremendous blood loss and lead to postoperative hemorrhagic anemia. The present study explored the efficacy and safety of improved intermittent-clamped drainage (ICD) for lower lumbar internal fixation.

Methods: This was a prospective study that included 156 patients with decompression of the spinal canal and internal fixation for the first time from January 2012 to December 2014. The patients were randomly divided into ICD group and CNPD group, and each group had 78 cases. A drainage tube was placed under the deep fascia in all patients within 10 min after the commencement of wound closure. The postoperative drainage amount at different time points, the hemoglobin level, and postoperative complications were recorded and compared between the two groups. Shapiro-Wilk test, independent samples *t*-test, and Mann-Whitney *U*-test were used in this study.

Results: The drainage amount was significantly reduced in the ICD group, as compared with the CNPD group ($Z = 10.74, P < 0.01$). The mean total drainage amount (in ml) of the single-segment and two-segment procedures was significantly greater in the CNPD group than the ICD group ($Z = 10.63$ and 10.75 , respectively; $P < 0.01$). For the adverse events, there was no significant difference in postoperative temperature, wound problem, and complications between the two groups.

Conclusions: The present study showed a statistically significant reduction in postoperative drainage amount between ICD and CNPD groups, and ICD is an effective, convenient, and safe method for routine use in lower lumbar surgery. It is essential to focus on the effect of clamping drainage with long-segment surgical procedure and complex lumbar disease in the further investigation, as well as the effect of clamping on long-term functional outcomes.

Key words: Blood Loss; Complications; Drainage; Lumbar Surgery

INTRODUCTION

Degenerative disease of the lumbar spine is often caused by compression of neural elements, which results in radicular pain and neurogenic claudication, weakness, numbness/tingling, and pain in the lower back/buttocks.^[1,2] Decompression of the spinal canal (DSC) is a common surgical procedure employed for various diseases of the lumbar spine, such as lumbar disc herniation (LDH), spinal stenosis (SS), and lumbar spondylolisthesis to alleviate intraspinal compression and subsequently relieve symptoms of nerve compression.^[3] However, DSC often involves the internal vertebral venous plexuses, as well as soft tissue in vertebral/paravertebral regions, and can cause massive blood loss from surgical wounds. Thus, the use of continuous negative pressure

drainage (CNPD) after surgery has become routine to prevent nerve compression caused by hematomas in surgical incisions as well as to reduce the incidence of postoperative bacterial infection.^[4-6] However, the use of CNPD after DSC remains somewhat controversial. It has been reported that CNPD after DSC and internal fixation can lead to tremendous blood loss and subsequent postoperative hemorrhagic anemia.^[7] In

Address for correspondence: Dr. Ming-Sheng Tan,
Department of Spinal Surgery, China-Japan Friendship Hospital,
Beijing 100029, China
E-Mail: zrtanms@sina.com

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recent years, several surgeons have suggested that placement of a drainage tube in wounds weakens the hemostasis of the tamponade effect in closed cavities, which increases postoperative blood loss.^[8,9] The aim of this study was to determine whether improved intermittent clamping of a drainage tube helps to reduce the drainage amount and avoid complications after DSC and internal fixation.

METHODS

Materials

This was a randomized, unblinded, prospective study, which was approved by the local Medical Ethics Committee. Written informed consent was obtained from all patients. A total of 156 patients with degenerative spinal disease who underwent DSC and internal fixation for the first time were enrolled from January 2012 to December 2014. All patients received same surgical procedure with single- or two-segment total laminectomy and posterior lumbar interbody fusion. A random number list was generated by computer and offered to every patient, patients who met inclusion criteria were randomly divided into intermittent-clamped drainage (ICD) group and CNPD group according to the order of hospital admission by another researcher: an ICD group ($n = 78$), which included patients who received improved ICD, and a CNPD group ($n = 78$), which included patients who received CNPD. The drain tube was placed under the deep fascia at the end of surgery in all patients within 10 min after the commencement of wound closure. These surgeries were performed by the same group of surgeons according to the standard practice at the China-Japan Friendship Hospital. Tube clamping was finished by another member of the study. The mean patient age was 55.8 years (range, 42–70 years) with a mean disease history of 10.9 months (range, 3–12 months). Patients' demographic and clinical data are shown in Table 1.

Inclusion criteria

Patients were included in the study if they met the following criteria: LDH, SS, or lumbar degeneration spondylolisthesis (DS) of the lumbar spine who underwent DSC of single or two segments involving internal fixation using lumbar pedicle screws, placement of a silicon drainage

tube (diameter, 5 mm) into the wound, and no complications related to drainage.

Exclusion criteria

Patients with preoperative use of anticoagulants; intraoperative injury to the dura and nerve, postoperative leakage of cerebrospinal fluid (CSF), severe abnormalities in liver function, and abnormalities in coagulation (i.e., prothrombin time, prothrombin ratio, and activated partial thromboplastin time) were excluded from the study.

Postoperative management

We used a visualized and convenient method to estimate pressure in the drainage cavity in the ICD group. The density (g/m^3) and pressure (centimeters of water, cmH_2O) of fluid in the drainage cavity were measured 6 h after the surgery. Drainage fluid (1 ml) was collected and weighed to determine the density according to the following formula: $\rho = m/V$, where ρ denotes density, m is the fluid mass, and V is the fluid volume. Pressure in the drainage cavity was estimated with the patients in the supine position using a ruler at the same vertical level as the drainage cavity (0 cm). Then, the medical staff would raise the drainage tube to the "35 cm" mark to observe and record the level of the drainage fluid [Figure 1]. Pressure was calculated using the following liquid pressure formula: $P = \rho \times g \times h$, where P is liquid pressure, g is the gravity at the surface of the overlying material, ρ is the density of the liquid, and h is the height of the liquid column.

In the ICD group, if deterioration of neural function (e.g., hypesthesia, weakening of ankle activity) was absent and pressure in the drainage cavity was $<35 \text{ cmH}_2\text{O}$, the drainage tube was clamped for the first 6 h. At each postoperative time point (i.e., 6 h, 12 h, 24 h, 48 h, and 72 h), the tube was opened for 10 min or upon reaching a drainage amount of 10–20 ml. If pressure in the drainage cavity was $<35 \text{ cmH}_2\text{O}$, the drainage tube was clamped. In the CNPD group, the drainage tube was opened continuously. The drainage was removed in both groups if drainage amount in 24 h was $<50 \text{ ml}$. Data collection was then conducted by medical staff who were blinded for the study purposes. Drainage amount parameters were the main results of interest. Drainage amount at each postoperative time point (i.e., 6 h, 24 h, 48 h, and 72 h) and total drainage amounts as well as the color and characteristics of the drainage in both groups

Table 1: Demographic and clinical data of the patients

Items	ICD group ($n = 78$)	CNPD group ($n = 78$)	t	P
Age (years)	56.4 ± 5.7	55.6 ± 6.3	0.83	0.40
BMI (kg/m^2)	25.4 ± 2.2	24.9 ± 2.5	1.33	0.09
Diagnosis				
LDH	25	26	—	—
SS	69	71	—	—
DS	17	13	—	—
Surgical segments				
Single segment	29	25	—	—
Two-segment	49	53	—	—

All data were expressed as mean \pm SD or n . ICD: Intermittent-clamped drainage; CNPD: Continuous negative pressure drainage; DS: Lumbar degeneration spondylolisthesis; LDH: Lumbar disc herniation; SS: Spinal stenosis; SD: Standard deviation; BMI: Body mass index.

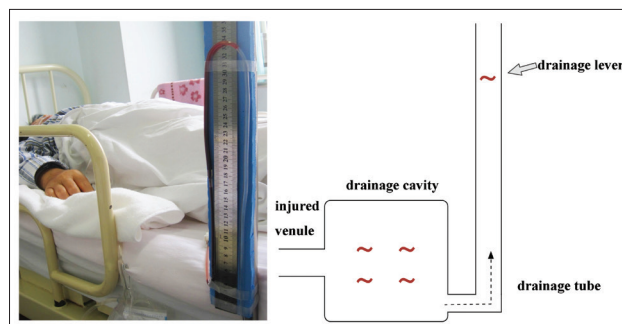


Figure 1: Pressure in the drainage cavity could be represented by the level of drainage fluid.

were recorded. In addition, the hemoglobin (Hb) level was measured in 24 h and 48 h postoperatively. The rehabilitation regimen was the same for all patients. Nerve function in the lower limbs was carefully observed. If deterioration of neural function was observed, computed tomography (CT) and magnetic resonance imaging (MRI) of the lumbar region were performed. And also, other postoperative complications were closely monitored. All patients received ultrasound examination of drainage cavity at day 1 postoperatively.

Statistical analysis

Data are presented as mean \pm standard deviation (SD). All statistical analyses were performed using SPSS software (IBM-SPSS, Inc., Chicago, IL, USA). Student's *t*-test was performed to compare the following variables: patient age, body mass index (BMI) index, operating room time, estimated blood loss, baseline and postoperative Hb, and postoperative temperature. Differences in drainage amount were analyzed by Mann-Whitney *U*-test. A $P < 0.05$ was considered statistically significant.

RESULTS

A total of 156 patients were recruited into the study. One patient with CSF leakage in the CNPD group was eliminated from the study. The following demographic parameters did not differ significantly between the ICD and CNPD groups: age, gender, BMI index, operating room time, estimated blood loss, and baseline Hb level [Table 2]. The CNPD group had significantly lower levels of Hb than those in the ICD group after surgery ($P = 0.04$) [Table 2]. The temperature in the first 24 h after surgery was higher in the ICD group as compared to the CNPD group, but there was no significant difference ($P = 0.20$), and it resolved by the next 24 h following surgery.

The mean pressure in the drainage cavity and drainage density were 34.5 ± 2.9 cmH₂O and 1.1 ± 0.1 g/m³,

respectively. Comparisons of drainage amounts at different time points are shown in Table 3. The drainage amount was significantly greater in the CNPD group as compared to the ICD group in 6 h to 48 h ($P < 0.01$). Especially in the first 24 h, the mean drainage amount in the ICD group was significantly less than those in CNPD group ($P < 0.01$). However, there was no significant difference between the two groups after 48 h ($P = 0.34$). The mean total drainage amount (in ml) of the one- and two-segment procedures was significantly greater in the CNPD group than the ICD group (272.1 ± 55.2 and 363.2 ± 62.3 vs. 95.6 ± 32.1 and 112.2 ± 33.2 , respectively, $P < 0.01$). Drainage amount of 66 cases (84.6%) in the ICD group was significantly reduced at 24 h after surgery. Moreover, the duration of drainage in these patients was 24–48 h after the surgery. On the other hand, drainage amount in CNPD group was reduced significantly at 48–72 h after the surgery. The duration of drainage was 48–72 h in 54 (70.1%) patients.

During the drainage period, no patient had infection and nerve compression in the clamped or the CNPD group. All patients received ultrasound examination of the drainage cavity which revealed that small hematoma and hydrops were found but did not result in neurologic deterioration. However, neural function deteriorated in five patients (two in the ICD group and three in the CNPD group), but this deterioration was not related to postoperative drainage. Results of emergency CT and MRI of the lumbar spine in these patients showed compression without obvious hematoma formation requiring drainage in three patients due to abnormal positioning of pedicle screws. Two of these patients underwent exploratory surgery within 12 h of primary surgery to adjust the pedicle screws, which resulted in marked improvement. Recovery of nerve function was observed in the rest of the three patients after treatment for dehydration and trophic nerves. The average follow-up period was 13 months; eight patients were lost to follow-up for no identifiable reason. The follow-up of these cases shows that wound infection or nerve compression caused by hematoma was not found.

DISCUSSION

CNPD is routinely used to prevent postoperative complications, such as epidural hematoma and associated neurologic compromise, following lower lumbar spine surgery. However, several orthopedic surgeons have recently suggested that placement of a drainage tube compromises hemostasis of the tamponade effect in closed cavities because CNPD cannot entirely circumvent hematoma formation.^[8,9] Some researchers have reported that CNPD promotes infection and even sometimes provokes a surgical site infection.^[10] Furthermore, it has been reported that 37% of blood loss occurs within 2 h and 55% occurs within 4 h after total knee arthroplasty.^[11] Thus, some authors have suggested that application of short-term clamped drainage in the early postoperative stage could reduce blood loss through the tamponade effect.^[9,12-14] Moreover, drainage of blood can prevent wound complications.^[15-17]

Table 2: Observation parameters of intermittent-clamped drainage group and continuous negative pressure drainage group

Parameters	ICD group (n = 78)	CNPD group (n = 78)	t	P
Operating room time (min)	183.1 \pm 40.2	179.6 \pm 36.4	0.57	0.57
Estimated blood loss (ml)	499.5 \pm 59.0	504.4 \pm 62.7	0.50	0.62
Hemoglobin (g/L)				
Baseline	133.4 \pm 11.8	132.5 \pm 13.6	0.44	0.66
Postoperation				
Day 1	121.7 \pm 13.4	117.4 \pm 12.5	2.07	0.04
Day 3	121.1 \pm 14.2	116.9 \pm 13.8	1.87	0.06
Temperature (°C)				
Day 1	37.53 \pm 0.41	37.45 \pm 0.36	1.30	0.20
Day 2	36.83 \pm 0.30	36.86 \pm 0.26	0.67	0.50

All data were expressed as mean \pm SD. ICD: Intermittent-clamped drainage; CNPD: Continuous negative pressure drainage; SD: Standard deviation.

This theory is also applicable to postoperative management after internal fixation of the lower lumbar spine. We found that DSC and internal fixation ensured large cavities in the stitched incision. Irrespective of how long CNPD was employed, bone defect and bone cavities caused by the internal fixation frame could not be filled, and CNPD only led to further blood loss primarily from the venous plexuses and capillaries after DSC and internal fixation. According to Pascal's law, pressure exerted anywhere in a confined incompressible fluid is transmitted equally in all directions throughout the fluid such that the pressure variations (initial differences) remain the same. Similarly, the drainage cavity becomes confined with the use of a clamped drainage tube so that the drainage fluid has the same pressure as the surrounding soft tissues and blood vessels. It has been reported that the pressure of the venous plexus ranges from 10 to 22 cmH₂O and capillary pressure is about 34 cmH₂O.^[18] In our study, the pressure in the drainage cavity was about 34.5 ± 2.9 cmH₂O, through observation of the fluid level in the elevated drainage tube, which is easy to operate with direct reading compared to using central venous pressure measuring device. Hence, blood in the drainage cavity could reach the same level of pressure as bleeding venous plexuses and capillaries [Figure 2], resulting in cessation of blood loss. On the contrary, when CNPD is applied, the drainage cavity is no longer confined. Therefore, the pressure of the drained fluid is much less than that of the venous plexus and capillaries, which could result in increased blood loss [Figure 3]. The results of our study are compatible with this point by comparing the drainage amount between the two groups, especially in the ICD group the mean drainage amount in the first 24 h was significantly less than

the amount of blood loss using CNPD. We also compared statistics between the two groups in the mean total drainage amount of the single- and two-segment procedures, and these results were positive. Therefore, clamped drainage can lead to raised pressure in drainage cavity, contributing to hemostatic effect, which is similar to tamponade effect by using clamped drainage after total knee arthroplasty. However, it remains uncertain whether clamped drainage could cause compression of the spinal cord and nerve, especially compression of the cauda equina. Fortunately, these consequences or other postoperative complications were not observed in the two groups, which suggest that the spinal cord in lower lumbar canal and cauda equina may be able to withstand the pressure from drainage fluid in these patients. However, long-term surgical procedure could cause more local tissue injury and bleeding, we did not know whether similar results can be obtained in long-term surgical procedure and these still need further study.

At present, there is no consensus on an optimal duration of clamped drainage, as some researchers believe that a longer clamping period is associated with an increased risk of postoperative complications, such as delayed wound healing, skin edge necrosis, hematoma, and infection.^[19] Moreover, drainage fluid in closed cavity is a potential risk factor, which may provide the circumstance for bacterial colonization. It was reported that the use of drainage tubes for more than 24 h may increase the risk of infection,^[10] and the infection rates range from 0.7% to 11.9% after lumbar surgery.^[20] In our study, not only the duration of drainage in both groups of patients was more than 24 h, but also the drainage needed clamping or opening by manual operating, so these may increase the incidence of infection. However, there was no statistically significant difference in postoperative temperature between the two groups in the present study [Table 2], and wound swelling and purulent exudate were not observed. Moreover, when drainage was opened in the ICD group, the off-clamped procedure was operating out of drainage cavity and the tube was natural flatted, so liquid back could not happen. Indeed, we believe that these procedures could not increase the incidence of infection.

Our drainage method also plays a role of safety valve to monitor pressure in drainage cavity. Active bleeding could

Table 3: Postoperative drainage amount (ml) at different time points

Time (h)	ICD group (n = 78)	CNPD group (n = 78)	Z	P
0–6	18.5 ± 5.8	105.5 ± 51.6	9.86	<0.01
6–12	16.3 ± 4.3	78.8 ± 40.8	10.07	<0.01
12–24	50.5 ± 6.2	76.5 ± 58.9	4.03	<0.01
24–48	52.2 ± 3.9	75.5 ± 49.6	4.30	<0.01
48–72	51.7 ± 5.9	56.5 ± 32.8	9.64	0.34
Total 0–72	189.2 ± 28.9	392.8 ± 50.4	10.74	<0.01

All data were expressed as mean ± SD. ICD: Intermittent-clamped drainage; CNPD: Continuous negative pressure drainage; SD: Standard deviation.

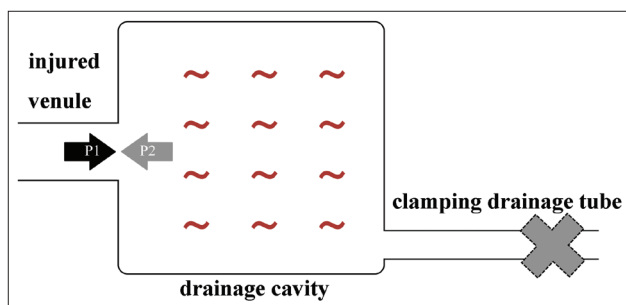


Figure 2: When the drainage tube is clamped, P1 = P2. P1: Pressure within the injured venule; P2: Pressure of the drainage fluid.

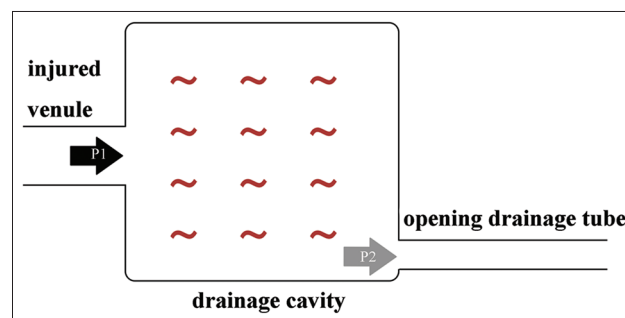


Figure 3: When the drainage tube is open, P1 > P2. P1: Pressure within the injured venule; P2: Pressure of the drainage fluid.

destroy the balance of pressure in drainage cavity which is mainly because of injury of the arterioles. At this time, drainage fluid would be over “35 cm” mark and drained out due to gravity and siphon principle, which lead to reduced pressure in drainage cavity to avoid nerve and soft tissue compression. Besides, the nerve function symptoms in the lower limbs was carefully observed in the ICD group. The color of the drainage fluid was also monitored, if the color change to clear that indicated cerebrospinal fluid (CSF) leakage. In the CNPD group, one case was eliminated because of CSF leakage. The prevalence of CSF leakage after surgery of the lower lumbar spine has been reported to be 2.31–9.37%,^[21] which may be due to placement of a drainage tube. In particular, CNPD can lead to clot absorption and negative pressure in the vicinity of arachnoidal wounds, which accelerates CSF leakage and adversely affects arachnoidal wound repair. Therefore, postoperative treatment and nursing should focus on the prevention of headaches due to low intracranial pressure, impaired wound healing, infection, and other complications associated with CSF leakage.^[22]

There were several limitations in our study. Although it was a prospective design, the operators were not blinded to the type of surgery. This study was unable to compare the different types of lumbar spinal canal decompression and lumbar interbody fusion. Patient allocation did not involve multi-segment degeneration. Moreover, MRI was used for observing the postoperative hematoma, but its three-dimensional volume was not measured. This study focused on comparing efficacy between the two-drainage method in controlling blood loss and complications, so it did not include functional scoring systems or patient satisfaction.

In conclusion, the present study showed that improved intermittent clamping of the drainage tube after lower lumbar internal fixation can significantly reduce blood loss and did not lead to obvious deterioration of neural function caused by compression of hematomas, wound infection, or other complications. Hence, improved intermittent clamping is an effective, convenient, and safe method for routine use in lower lumbar surgery. It is essential to focus on the effect of clamping drainage with long-segment surgical procedure and complex lumbar disease in the further investigation, as well as the effect of clamping on long-term functional outcomes and patient satisfaction.

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Conflicts of interest

There are no conflicts of interest.

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