



Negative versus natural drainage after single-level posterior lumbar interbody fusion. A prospective randomized study



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ABSTRACT

Introduction: Despite of their extensive use, drains remain controversial without clear guidelines, and there is unclear evidence on drain use in spine procedures. Negative pressure drainage is theoretically more effective in preventing postoperative hematomas. On the contrary, it may result in excessive drainage and blood loss. The aim of this study was to compare the outcome between the uses of negative versus natural drainage in single level posterior lumbar interbody fusion (PLIF).

Research question: The aim is to compare between negative versus natural drainage after single-level PLIF as regard to postoperative wound infection, wound healing, temperature, pain and neurological deficits.

Materials and methods: A prospective randomized study of consecutive PLIF patients at a single level for lumbar disc prolapse was performed between January 2019 and January 2020. The patients were randomly assigned to either the negative suction drainage group or natural drainage group. Negative suction was created by maximum compression of the reservoir to create negative pressure. In the other group, natural pressure drainage was kept without any negative pressure.

Our study included a total of 62 patients who met the inclusion criteria. They were divided into two groups; 33 patients had negative suction drains and 29 patients had natural drainage. There were 32 female (51.6%) and 30 male (48.4%). Their ages ranged between of 23–69 years, with a mean age of 42.11 ± 8.89 years.

Results: Drainage volume was statistically higher in the negative group on the day of surgery (day 0) as well as the 1st and second days after. However, no significant differences were observed as regards to postoperative temperature, pain, wound infection, temperature, or neurological deficits.

Discussion & conclusion: In this prospective randomized study, our results revealed that natural drainage in short term can reduce the total amount of blood in the drain, and therefore the blood loss without significant differences in postoperative wound infection, wound healing, temperature, pain, or neurological deficits in single-level PLIF.

1. Introduction

Closed drains are commonly used in orthopaedic surgeries, particularly in spinal procedures, and is thought to prevent hematoma formation (Payne et al., 1996; Kanayama et al., 2010). The incidence of postoperative hematoma ranges between 0.2 and 2.9% (Kou et al., 2002; Awad et al., 2005; Scuderi et al., 2005). Postoperative hematoma can increase wound tension and delay healing, and it is considered as an excellent culture medium for infections and wound complications. In addition, epidural hematoma may result cauda equina compression and neurological deficits (Payne et al., 1996; Mirzai et al., 2006). In contrast,

closed suction drainage could cause postoperative fever, pain, anxiety, and discomfort and predispose the patients to infection. Furthermore, it increases postoperative blood loss, and the need for transfusion (Zhou et al., 2013; Walid et al., 2012).

Negative pressure drainage is theoretically more effective in the prevention of postoperative hematomas. On the contrary, it may result in excessive drainage and blood loss (Chen et al., 2020).

Despite of their extensive use, drains remain controversial without clear guidelines, and there is little evidence of drain use in spinal procedures, including drain types, indication, depth of placement, duration, and the time of removal based on fixed time or drain volume (Payne

Abbreviations: PLIF, Posterior Lumbar Interbody Fusion.

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et al., 1996; Kanayama et al., 2010; Blank et al., 2003; Brown and Brookfield, 2004; Diab et al., 2012; Liu et al., 2016; Sen et al., 2005).

To help address this debate, we conducted a prospective randomized clinical study aiming at comparing the outcome between the uses of negative versus natural drainage drains in single level discogenic posterior lumbar interbody fusion (PLIF). We are unaware about similar studies in the literature.

2. Materials and methods

2.1. Study design and patient selection

A prospective randomized study of consecutive PLIF patients at a single level for lumbar disc prolapse was performed between January 2019 and January 2020.

The institutional board and ethics committee of our center approved the study protocol. An informed consent was obtained from every patient.

The diagnosis of lumbar disc herniation was based on clinical examination and radiological examination including MRI and plain X-ray examination. Indications for surgery were extensive or intractable radicular and back pain and or neurologic deficit.

Exclusions criteria included patients who underwent multisegmental lumbar surgery, infection, spondylolithesis, revision surgeries, abnormal coagulation function, and intraoperative and postoperative cerebrospinal fluid leakage.

Our study included a total of 62 patients who met the inclusion criteria. They were divided into two groups, 33 patients had negative suction drains and 29 patients had positive drains. There were 32 female (51.6%) and 30 male (48.4%). Their ages ranged between of 23–69 years, with a mean age of 42.11 ± 8.89 years.

2.2. Surgical procedures

Surgery was performed in the prone position after general anesthesia and endotracheal intubation. On anesthesia induction, systemic prophylactic antibiotic therapy with Teicoplanin (Targocid) was administered intravenously at a dosage of 400 mg (Bryson et al., 2016; <https://online.boneandjoint.org.uk/doi/full/10.1302/0301-620x.98b8.37359?journalCode=bj.Pubmed> Partial stitle stitle Volume, 1302). PLIF was performed in the standard way by two experienced consultant spinal surgeons. Midline skin incision was used to expose the posterior elements. Pedicle screws were applied to the surgical segment by the freehand technique. The pedicle screws used were 6.2 mm screws of 40–50 mm length (EgyFix Co., Egypt). The position of the screws was checked using AP and lateral views on the C-arm. A fenestration was made at the affected site with complete removal of the ligamentum flavum and decompression of the distal nerve root. In lumbar canal stenosis, decompression was made on both sides when necessary. Discectomy down to the exposed endplate was performed using a series of shavers and curettes. Care was taken to ensure complete nerve root decompression. Autogenous local bone graft and metal or polyetheretherketone (PEEK) cages of appropriate size were placed and impacted in the space (EgyFix Co., Egypt). The surgery was performed under hypotensive anesthesia in which systolic blood pressure was kept to less than 90 mm Hg. Before wound closure, blood pressure was returned to normotension. Haemostasis with a bipolar electrocoagulation and gel foam were used when necessary. If incidental durotomy occurred during surgery, patients were excluded from the study.

Before wound closure, closed drainage was placed under the deep fascia. The drain tube was attached to a closed suction reservoir (VACUGMS, GMS, Barcelona, Spain- Tube size: 14 Fr).

The patients were randomly assigned to either the negative suction drainage group or the natural drainage group. Negative suction was created by maximum compression of the reservoir to create negative pressure. In the natural drainage group, natural pressure drainage was

kept without any negative pressure (Fig. 1A and B). The type of drain to be used was decided based on double-blind simple randomization using the application Choose Random (The Randomizer). (<https://apkpur.com/choose-random-the-randomizer-random-generator>).

2.3. Post-operative care

A complete neurological examination was done in all patients following recovery from anesthesia. Systemic antibiotics were given for two days; four hundred milligrams of teicoplanin every 24 h. Appropriate analgesics were given for the first week post-operatively. The drain was removed on the third postoperative day when volume of drain was 50 mL or less/day.

We did not use any thromboprophylactic drug in the postoperative period, as all patients had started mobilization immediately in the first day. In addition, none of our patients included in the study received anti-platelet agent that required cessation before surgery. In addition, none of the patients had received any antifibrinolytic agent. Blood transfusion was not required in any patient.

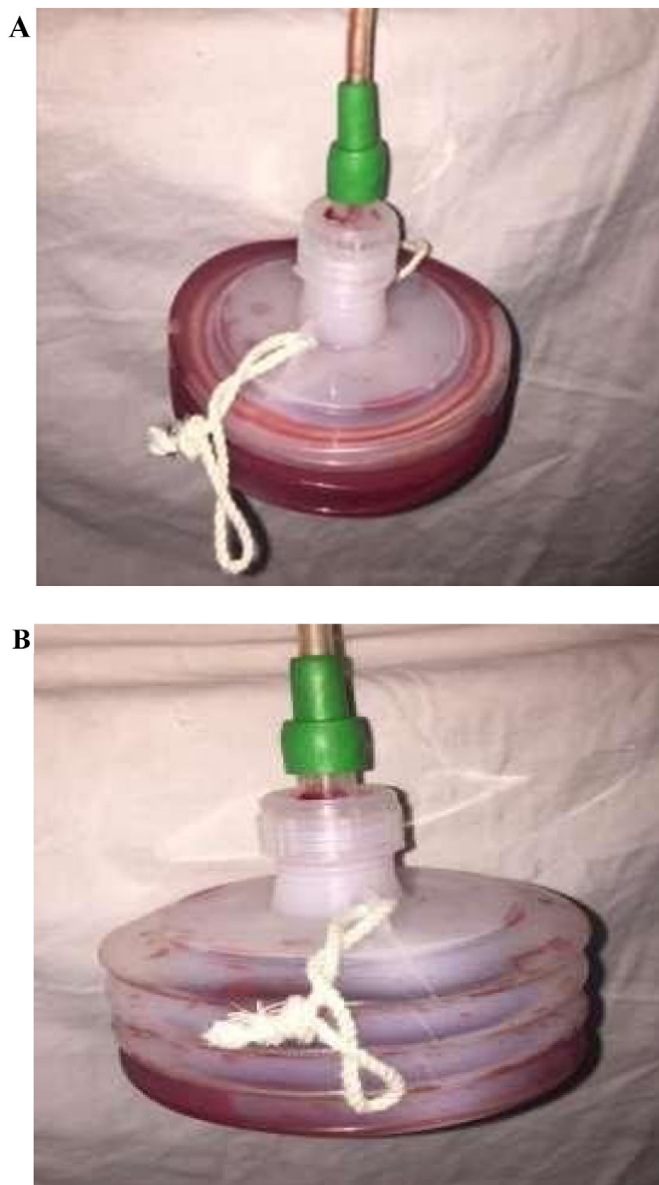


Fig. 1. A: Negative suction drain. B: Natural pressure drain.

2.4. Follow up

Clinical and radiological follow up of patients was done immediately postoperatively. Patients were followed up for a total duration of three months.

2.5. Statistical analysis

The following data were recorded: age, gender, the drainage volume, postoperative temperature, hemoglobin, pain according to visual analogue scale (VAS), total drainage days, and postoperative complications. Continuous data are presented as mean ± standard deviation. All statistical analysis was performed using SPSS version 24.0 (SPSS Inc, Chicago, IL), and a P value < 0.05 was considered statistically significant.

3. Results

Comparison between negative and natural drainage according to demographic data was demonstrated in Table 1.

3.1. Drainage volume

Drainage volume was higher in the negative group on the day of surgery (day 0), as well as the first and second days after. This was highly statistically significant (Table 2).

3.2. Postoperative hemoglobin level

Hemoglobin levels were recorded pre-operative and up to day 2. A statistical significance was noted in the pre-operative hemoglobin, which was significantly higher in negative drains (Mean 13.29 ± 1.26) compared to natural drainage (mean 12.50 ± 1.48). In addition, there was a high statistical significant difference between the pre-operative hemoglobin and hemoglobin on day 2 in each drain type (Table 3).

3.3. Postoperative temperature

When comparing temperature readings of the 62 patients in this study, we found that there was no statistical significant difference between negative and natural drainage. P = 0.194, 0.334, 0.607 in days 0, 1 and 2 respectively.

3.4. Pain according to visual analogue scale (VAS)

We found that a significant statistical difference in each drain type throughout days 0, 1, and 2 (Table 4). However, no statistical differences were found between active and passive drains in each period (Tables 4 and 5).

Table 1
Comparison between negative and natural drainage according to demographic data.

	Total (n = 62)		Drain				Test of Sig.	p
	No.	%	Negative (n = 33)		Natural drainage (n = 29)			
No.			%	No.	%	No.	%	
Sex								
Male	30	48.4	16	48.5	14	48.3	$\chi^2 = 0.0$	0.987
Female	32	51.6	17	51.5	15	51.7		
Age (years)								
Min. – Max.	23.0–69.0		23.0–54.0		24.0–69.0		t = 0.191	0.849
Mean ± SD.	42.11 ± 8.89		41.91 ± 7.52		42.34 ± 10.37			
Median (IQR)	43.0(37.0–48.0)		43.0(38.0–46.0)		44.0(33.0–48.0)			

χ (Kanayama et al., 2010): Chi-square test t: Student t-test.
p: p-value for comparing between negative and natural drainage.

3.5. Complications

Two patients out of 62 (3.2%) were complicated by wound infection (one superficial and one deep) of the total number of surgeries performed.

The first one was a 47 year old diabetic female patient from the natural drainage group with L4-5 disc prolapse. She came back two week after surgery with superficial wound infection. Debridement was performed which revealed that the infection was only superficial and not beyond the deep fascia. The wound condition was completely improved after debridement and systemic antibiotics. The second one was a 38-year male patient from the negative drain group with L5-S1 disc prolapse. Deep wound infection was developed on the third postoperative day. She underwent debridement which revealed that the infection was deep to the deep fascia. The wound was also improved following debridement and systemic antibiotics.

Throughout the study, there were no cases with wound hematoma or worsening of the preoperative neurological status.

4. Discussion

Although there is no sufficient evidence to support the application of closed suction drains for posterior spinal surgery, it is still a common practice with a thought of decreasing postoperative hematoma formation with all its complications (Kanayama et al., 2010; Brown and Brookfield, 2004; Aono et al., 2011; Cramer et al., 2009; Patel et al., 2017). Even with drain use, there no consensus regarding the way of closed drainage whether negative or natural drainage.

To the best of our knowledge this is the first prospective randomized study comparing the outcome between the uses of negative versus natural drainage in single level discogenic PLIF. Although there are few studies comparing “drain” versus “no-drain” (Mirzai et al., 2006; Walid et al., 2012; Brown and Brookfield, 2004; Payne et al., 1996), we could find only one recent study about this subject by Chen et al. However, their study was retrospective (Chen et al., 2020).

Throughout the study, we did not report any case with symptomatic postoperative wound hematoma. The incidence of asymptomatic hematomas has been reported at high rates (33–100%) (Ahn et al., 2016). It seems that wound drainage is not the only factor which prevents hematoma, which was supported by some previous studies (Kou et al., 2002; Awad et al., 2005; Kebaish and Awad, 2004; Amiri et al., 2013). Intraoperative adequate hemostasis plays a very important role. We think that wound drains could be beneficial in some situations when adequate hemostasis is difficult or impossible because of the proximity of the epidural venous plexus near to the nerve roots, when hypertension may occur after surgery, or when postoperative anticoagulant therapy is mandatory in high risk patients. In terms of hematoma, we were unable to state wheatear a negative or a natural drainage drain is better. However, we agree with the observation of Chen et al. that natural one can allow drainage without suction force which allows some blood to

Table 2
Comparison between negative and natural drainage drains according to the drain volume.

Drain Volume	Total (n = 62)	Drain		U	p
		Negative (n = 33)	Natural drainage (n = 29)		
Day 0					
Min. – Max.	100.0–600.0	200.0–600.0	100.0–400.0	95.0*	<0.001*
Mean ± SD.	317.7 ± 115.62	389.4 ± 97.43	236.2 ± 73.07		
Median (IQR)	300.0(200.0–400.0)	400.0(300.0–400.0)	200.0(200.0–300.0)		
Day 1					
Min. – Max.	50.0–500.0	100.0–500.0	50.0–200.0	157.50*	<0.001*
Mean ± SD.	157.3 ± 79.37	197.0 ± 85.64	112.1 ± 36.97		
Median (IQR)	150.0(100.0–200.0)	200.0(150.0–200.0)	100.0(100.0–100.0)		
Day 2					
Min. – Max.	50.0–500.0	50.0–500.0	50.0–500.0	231.50*	<0.001*
Mean ± SD.	83.87 ± 81.87	96.97 ± 79.0	68.97 ± 83.89		
Median (IQR)	50.0(50.0–100.0)	100.0(50.0–100.0)	50.0(50.0–50.0)		

U: Mann Whitney test. p: p-value for comparing between negative and natural drainage drains.

*: Statistically significant at $p \leq 0.05$.

Table 3
Comparison between negative and natural drainage drains according to hemoglobin.

Hemoglobin	Total (n = 62)	Drain		t	p
		Negative (n = 33)	Natural drainage (n = 29)		
Pre					
Min. – Max.	10.20–17.0	10.50–16.0	10.20–17.0	2.270*	0.027*
Mean ± SD.	12.92 ± 1.41	13.29 ± 1.26	12.50 ± 1.48		
Median (IQR)	12.85(12.0–13.50)	13.10(12.50–14.0)	12.30(11.50–13.0)		
Day 0					
Min. – Max.	8.80–15.10	9.80–15.0	8.80–15.10	1.101	0.275
Mean ± SD.	11.70 ± 1.18	11.85 ± 1.02	11.52 ± 1.34		
Median (IQR)	11.60(11.0–12.30)	12.0(11.30–12.20)	11.50(10.50–12.50)		
Day 1					
Min. – Max.	9.80–15.0	9.80–15.0	9.80–15.0	0.576	0.567
Mean ± SD.	11.57 ± 1.12	11.65 ± 1.04	11.48 ± 1.23		
Median (IQR)	11.50(11.0–12.0)	11.60(11.0–12.0)	11.50(10.50–12.50)		
Day 2					
Min. – Max.	9.50–15.0	9.50–15.0	9.80–15.0	0.146	0.884
Mean ± SD.	11.50 ± 1.14	11.52 ± 1.07	11.47 ± 1.24		
Median (IQR)	11.50(10.50–12.0)	11.50(11.0–12.0)	11.50(10.50–12.50)		
P_1	<0.001*	<0.001*	<0.001*		

t: Student t-test.

p: p-value for comparing between **negative and natural drainage**.

p1: p-value for paired – test for comparing between pre and day 2. *: Statistically significant at $p \leq 0.05$.

accumulate and therefore could accelerate the coagulation process (Chen et al., 2020).

Postoperative infection is one of the most commonly observed complications in spine surgery, occurring in 2.2%–8.5% of cases where instrumentation is required. Some studies have shown infection rates that reach as high as 20% (Rickert et al., 2016). In our study, we observed infection in two patients out of 62 in (3.2%) of the total number of surgeries performed; one recorded in each group, which was comparable with the Chen et al. study which included three cases of superficial infection out of 132 (Chen et al., 2020). Other studies comparing the outcome with and without drains outlined that there was no statistical difference in the development of infection (Patel et al., 2017; Waly et al., 2015).

An important and expected finding of this study was the drain volume which reflected the blood loss. Negative drains had a greater propensity for blood loss than natural drainage ones. The drain volume throughout each day in negative drains was significantly higher than that in natural drains. This was supported by the results of Chen et al. who revealed that natural pressure drainage without negative force decrease drainage volume and blood loss (Chen et al., 2020).

In addition, several studies comparing the use of drains versus non drains revealed that the use of drains definitely increases postoperative blood loss and blood transfusions requirement regardless of the number of spinal levels operated upon (Walid et al., 2012; Gubin et al., 2019; Muthu et al., 2020; Reier et al., 2022).

In their recent systemic review, Reier et al. revealed that drains are associated with increased blood loss, a greater chance of requiring blood transfusions, and longer hospital stays with the highest-quality studies (Reier et al., 2022).

Another recent systemic review and meta analysis by Muthu et al. found that the use of drains did not confer any benefit but only increased the total blood loss in multilevel thoracolumbar surgery (Muthu et al., 2020), which was concurrent with the recommendation by Waly et al. in their review on the subject (Waly et al., 2015). In another systematic review, Patel et al. found those with drains had a 23.9% chance of requiring blood transfusion, compared to 6.8% in those without drains (Patel et al., 2017).

Apart of the hematoma and postoperative infection, postoperative pain remains an important issue. In our study, there was no statistical difference between the average VAS score for the lower limbs between

Table 4
Pre and postoperative negative and natural drainage drains according to pain VAS.

Pain VAS	Pre	Day 0	Day 1	Day 2	Fr	p
Total (n=62)						
Min. – Max.	5.0–10.0	2.0–7.0	1.0–7.0	1.0–6.0	152.875*	<0.001*
Mean ± SD.	7.58 ± 1.02	4.29 ± 0.96	3.21 ± 0.98	2.60 ± 0.90		
Median (IQR)	8.0(7.0–8.0)	4.0(4.0–5.0)	3.0(3.0–4.0)	2.0(2.0–3.0)		
P0		<0.001*	<0.001*	<0.001*		
Sig. bet. Per.		p ₁ <0.001*,p ₂ <0.001*,p ₃ =0.010*				
Negative (n=33)						
Min. – Max.	5.0–9.0	2.0–7.0	2.0–7.0	2.0–6.0		
Mean ± SD.	7.64 ± 1.06	4.42 ± 0.94	3.18 ± 0.98	2.61 ± 0.83		
Median (IQR)	8.0(7.0–8.0)	5.0(4.0–5.0)	3.0(3.0–3.0)	2.0(2.0–3.0)	83.534*	<0.001*
P0		0.001*	<0.001*	<0.001*		
Sig. bet. Per.		p ₁ =0.002*,p ₂ <0.001*,p ₃ =0.105				
Natural drainage (n=29)						
Min. – Max.	5.0–10.0	3.0–7.0	1.0–7.0	1.0–6.0		
Mean ± SD.	7.52 ± 0.99	4.14 ± 0.99	3.24 ± 0.99	2.59 ± 0.98		
Median (IQR)	8.0(7.0–8.0)	4.0(3.0–5.0)	3.0(3.0–4.0)	2.0(2.0–3.0)	69.735*	<0.001*
P0		0.001*	<0.001*	<0.001*		
Sig. bet. Per.		p ₁ =0.042*,p ₂ <0.001*,p ₃ =0.042*				

Fr: Friedman test, Sig. between. periods was done using Post Hoc Test (Dunn's). *: Statistically significant at p ≤ 0.05.
p: p-value for comparing between the different periods P0: p-value for comparing between Pre and each other periods. P1: p-value for comparing between Day 0 and Day 1 p2: p-value for comparing between Day 0 and Day 2 p3: p-value for comparing between Day 1 and Day 2.

Table 5
Comparison between negative and natural drainage drains according to Pain VAS.

Pain VAS	Total (n = 62)	Drain		U	p
		Negative (n = 33)	Natural drainage (n = 29)		
Pre					
Min. – Max.	5.0–10.0	5.0–9.0	5.0–10.0	422.0	0.397
Mean ± SD.	7.58 ± 1.02	7.64 ± 1.06	7.52 ± 0.99		
Median (IQR)	8.0(7.0–8.0)	8.0(7.0–8.0)	8.0(7.0–8.0)		
Day 0					
Min. – Max.	2.0–7.0	2.0–7.0	3.0–7.0	373.0	0.115
Mean ± SD.	4.29 ± 0.96	4.42 ± 0.94	4.14 ± 0.99		
Median (IQR)	4.0(4.0–5.0)	5.0(4.0–5.0)	4.0(3.0–5.0)		
Day 1					
Min. – Max.	1.0–7.0	2.0–7.0	1.0–7.0	443.5	0.575
Mean ± SD.	3.21 ± 0.98	3.18 ± 0.98	3.24 ± 0.99		
Median (IQR)	3.0(3.0–4.0)	3.0(3.0–3.0)	3.0(3.0–4.0)		
Day 2					
Min. – Max.	1.0–6.0	2.0–6.0	1.0–6.0	470.0	0.895
Mean ± SD.	2.60 ± 0.90	2.61 ± 0.83	2.59 ± 0.98		
Median (IQR)	2.0(2.0–3.0)	2.0(2.0–3.0)	2.0(2.0–3.0)		
Decrease	↓4.98 ± 1.64	↓5.03 ± 1.63	↓4.93 ± 1.69	442.50	0.599

U: Mann Whitney test.
p: p-value for comparing between negative and natural drainage. Decrease: decrease between pre and day 2.

the two groups. However, on comparing each drain group separately throughout day 0 to day 2, it appeared to be a significant statistical

difference which was attributed to the success of the procedure itself and not the drains. Comparative studies between the use of a post-operative drain or not revealed no significant difference regarding the post-operative pain, which means that the use or not of the drain does not interfere with the increase or reduction of pain (Muthu et al., 2020). On the contrary, some other reports revealed that closed suction drainage could cause postoperative pain, anxiety, and discomfort (Zhou et al., 2013; Walid et al., 2012).

We could not found any statistical significant difference between negative and natural drainage as regards to the postoperative temperature. Our finding was supported by Chen et al. study who revealed that the body temperature was similar between the two groups (Chen et al., 2020). In their study comparing drainage versus non-drainage for single-level lumbar discectomy, Guo et al. observed that fever rate in the drainage group (18.7%) was less than that in the non-drainage group (28.2%). Their explanation was that the absorption of hematoma after surgery is associated by low grade fever. Since there is no clear correlation between postoperative fever and drains, surgeon should consider other noninfectious causes, especially in the first 48 h after surgery like the inflammatory stimulus of surgery, deep vein thrombosis, or drug fever.

5. Limitations

We acknowledge several limitations in our study. First, we narrowed our study group to single-level PLIF patients. Our choice was because it is one of the most popular and routine spinal procedures and the relatively lower incidence of spinal epidural hematoma compared to other extensive multisegmental lumbar procedures, therefore our findings should be applied only to single-level PLIF and should not be extended to multi-segmental ones. Second, the sample size was small, which may not have the strong evidence to make rigid conclusions or strong recommendations. Third, we did not perform postoperative MRI to assess extradural hematoma in our cases; therefore we were unable compare the incidence of small asymptomatic hematoma in both groups which may theoretically contribute to epidural fibrosis on long term. Forth, the follow-up period in the present study may not be enough to assess epidural fibrosis or the late infection which might have implications in understanding the long-term effect of using a drain. Furthermore, we did not include some parameters which may have impacts on the outcome like the body weight, body mass index, operative time, intraoperative blood loss and the necessity for blood replacement.

However, and within the context of its limitation, to the best of our knowledge, the present study was the first prospective randomized study to investigate the outcome between the uses of negative versus natural pressure drainage in single level discogenic PLIF.

6. Conclusions

Our data revealed that natural pressure drainage in short term can reduce the total volume of drain, and therefore the blood loss without significant differences in postoperative wound infection, wound healing, temperature, pain, or neurological deficits in single-level discogenic PLIF.

We recommend further high quality studies involving larger number of patients and a longer period of follow up to compare the outcome of drain use in cases with different pathologies, including lithesis, revision surgeries, and multilevel instrumentations, with inclusion of certain comorbidities, such as diabetes mellitus and hypertension to assess the impact on the choice of the drain status. Until that, the decision for using positive versus negative pressure drainage could be individualized.

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Author contribution

Tarek Elfiky: the design of the work, the surgical procedures, drafting and revision of the work.

Mahmoud El Sayed Mohammed Nafady: the surgical procedures and drafting of the work.

Ramy Nashaat Saad Lotfy Shehata: data collection and analysis and drafting the work.

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Declaration of competing interest

Declaration of competing interest: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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