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ORIGINAL ARTICLE

Role of closed drain after multi-level posterior spinal surgery in adults: a randomised open-label superiority trial

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Abstract

Purpose To explore the role of closed suction drain in multi-level posterior spinal surgery.

Methods We performed prospective, open-label, randomised control, superiority trial with parallel design and 1:1 allocation. A total of 161 patients undergoing posterior spinal surgery involving more than one motion segment at a dedicated spine surgery department were randomly allocated into "drain" or "no-drain" groups, based on which surgical drain was employed at the end of surgery. After excluding six cases with intraoperative dural tear, the data of 80 patients in "drain" and 75 patients in "no-drain" group were analysed. Primary outcome was total perioperative blood loss (sum of intraoperative blood loss, volume of drain if present and volume aspirated if patient developed collection in relation to surgical wound). The secondary outcomes were transfusion requirements, wound healing and complications.

Results Both groups were comparable with respect to baseline characteristics. Total perioperative blood loss was significantly higher in "drain" group (716 ± 312.97 ml vs 377.9 ± 295.72 ml, $p < 0.0001$). Number and volume of post-operative aspirations were significantly higher in "no-drain" group whereas transfusion requirements were significantly higher in "drain" group. Except for one case of superficial wound inflammation in either group, there were no complications. Subgroup analysis revealed that the results were applicable for surgeries involving "two/three" levels and "more than three" levels.

Conclusions The practice of not using closed surgical drains after multi-level posterior spinal surgery reduces post-operative blood loss and transfusion requirements. But this comes with the disadvantage of increased wound soakage and need for post-operative wound aspirations. The risks of benefits of "drain" and "no drain" must be carefully weighed and an informed choice be taken.

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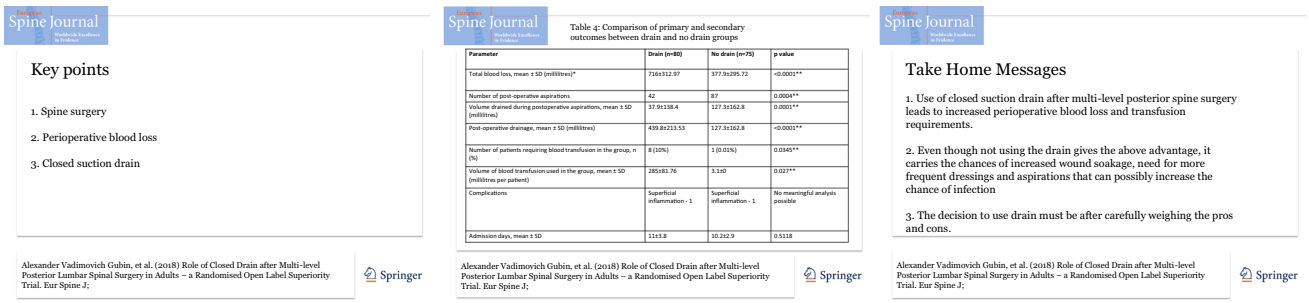
Extended author information available on the last page of the article

Graphical abstract These slides can be retrieved under Electronic Supplementary Material.



Keywords Spine surgery · Perioperative blood loss · Closed suction drain

Introduction

The use of post-operative suction drain is considered standard of care in posterior spinal surgery. This is based on the assumption that it decompresses the surgical wound preventing wound soakage, haematoma, gaping of the wound, fibrosis and infections [1, 2]. However, the role of drain in orthopaedic surgery is debated [3].

Several studies have suggested that the use of drain is not effective in preventing infection; in reality it may increase the rate of complications after surgery [4–6]. Drain may cause inflammation at skin interphase and act as a pathway for infection from outside. In addition, drain may prevent tamponade and pose increased chance of anaemia and blood transfusion [7]. Furthermore, drain may be difficult to remove and, in some cases, require additional surgery for removal especially if they are inadvertently sutured to surrounding tissues. Drain may be displaced or forcibly removed by confused patients causing additional trauma [8]. Finally, drain may add to treatment cost and length of hospital stay.

This debate is more relevant is spine surgery to see whether drain has a role in preventing the highly morbid complication of epidural haematoma, even if at the expense of increased risk of blood loss or infection [9]. Randomised control trials (RCTs) on the subject generally report that post-operative drain is not effective preventing haematoma and infection after spine surgery [10, 11]. On the other hand, a study on drain versus no drain in idiopathic scoliosis conflicted this finding, reporting decreased wound complications with use of drain without increasing the need for blood transfusion [12].

The available systematic reviews and meta-analysis on the subject do not support the use of closed drains. All of them consistently acknowledge the limited and poor quality of the evidence currently available and the need for well-designed studies in future [13–15]. In this background, we undertook a prospective randomised trial to compare the outcome of multi-level lumbar spine surgeries with and without post-operative suction drain. We hypothesised that outcome would be similar in both groups.

Materials and methods

Our study was designed as a prospective, open-label, randomised control, superiority trial with parallel design and 1:1 allocation. The study was approved by the Institute Ethics Committee. All patients between the ages of 18–80 years posted for posterior spinal surgery involving more than one motion segment were considered for the study. Informed consent was taken from all patients and enrolment was done prior to intervention. The inclusion criteria were skeletally mature patients, posterior spinal surgery for any reason (trauma, spinal canal stenosis, spondylolisthesis, deformity or tumour) and willingness to participate in study and follow-up. The following patients were not considered for the study—posterior spinal surgery involving single level (like single-level discectomy where we do not use drain as practice) and any approach other than posterior approach. The presence of infectious pathology (like spondylodiscitis, tuberculosis), presence of coagulopathies or bleeding disorders, history of treatment with antiplatelet drugs and anti-coagulants were other exclusion criteria. The study was performed in a tertiary-level referral teaching institute in a department dedicated to spine surgery.

We selected difference in total blood loss (TBL) as primary outcome. This is the sum of intraoperative blood loss (IBL) plus total volume of drain output and post-operative wound aspirate, if any. We considered IBL along with post-operative losses because it is the TBL (and not drain output and aspirations alone) that is clinically relevant and determine post-operative transfusions. We confined ourselves to directly measurable blood losses to improve

the external validity of our study findings. We did not account for haemoglobin drop and calculate the hidden blood loss as it is controversial with multiple formulae described in the literature without clear consensus [16]. We assumed that the hidden blood loss would be identical in both groups. The secondary outcomes defined were the difference in the following variables—number and volume of wound aspirations if any, need for post-operative blood transfusions, duration of admission and incidence of wound complications and infection.

Sample size was determined using sample size calculator for continuous outcome superiority trial from www.sealedenvelope.com [17]. The values were based on the meta-analysis by Liu et al. [14]. It included three studies that accounted for TBL, which is our primary outcome [10, 12, 18]. From the pooled data of these three studies, we calculated that the mean TBL was 771.13 ml and 807.74 ml in "drain" and "no-drain" groups, respectively, with standard error (SE) of outcome 68.36 ml. Assuming chosen significance (alpha) as 2.5% and power (1-beta) as 80%, our sample size estimation revealed a total of 134 patients, 67 in each group. We continued to recruit patients till 67 in each group had the required follow-up of 6 weeks. Thus the final sample size was 155: 80 in drain group and 75 in no-drain group.

Patients were randomised to "drain" group and "no-drain" group by an independent allocator using block randomisation method with randomly mixed block sizes of two, four and six, with sizes of block concealed from the executer. The independent allocator made random allocation cards in sealed envelopes using computer-generated random numbers. A duplicate set was made in case individual code breaking was required. The sequentially labelled sealed envelopes were made available to the operating surgeon just prior to wound closure who accordingly closed the wound without drain ("no-drain" group) or with two drains—one in the epidural space and one in paraspinal area exiting through separate stab incisions and connected to a common suction bulb ("drain" group). The patient or the investigator could not be blinded as the intervention was obvious.

During the period October 2015 to June 2017, 178 patients underwent posterior spinal surgery involving two or more motion segments. All patients enrolled into the study were operated by three consultant spine surgeons of the same level of qualification and experience. Two of them were present during every surgery and all operating surgeons adhered to the drain insertion protocol of the study. All patients were screened for eligibility, and 17 patients were excluded as they did not meet inclusion criteria. Six patients were excluded after randomisation (2 in "drain" group and 4 in "no-drain" group due to intraoperative dural tear). Thus 155 patients participated in the study: 80 in drain group and 75 in no-drain group. A flow diagram showing the enrolment of patients, allocation of treatment, and completion of the study is depicted in Fig. 1.

One of the authors collected all the data pertaining to the study. The demographic and clinical data included age, gender, body weight, comorbidities and indication for spinal surgery. Intraoperatively, duration of surgery, blood loss, length and depth of the surgical wound were noted. The same author followed up the drain output on a daily basis and calculated the total drain output. Wounds were inspected and dressed once daily for the first 3 days and thereafter just before discharge from the hospital. In between the wounds were inspected only if there was external soakage, and that too at a maximum frequency of once in 2 days. No evidence of drain for the previous 12 h guided drain removal. The time of discharge from inpatient stay was decided by satisfactory signs of wound healing in progression and post-operative recovery. The wounds were examined for any evidence of collection (as evidenced by fluctuant swelling) and if present were aspirated with a wide-bore needle under all aseptic precautions. The volume was noted at each aspiration, and all samples were submitted entirely for microbiological examination. Blood transfusion was administered if Hb level was < 8 g/dL or for symptomatic patient with Hb between 8 and 10 g/dL. The symptoms that would prompt transfusion were any combination of persistent tachycardia (heart rate > 100 for at least 4 h), lassitude (inability to comply with physical therapy exercises), chest pain, dyspnoea and hypotension (a fall in systolic blood pressure > 20 mm Hg) in appropriate clinical context [19]. Post-operatively the following variables were captured—need of aspirating the wound, volume at each aspirate, number and volume of blood transfusion needed, number of admission days and complications, if any. Sutures were removed at 2 weeks in the out-patient department. All patients were again evaluated at 6 weeks from surgery, and all surgical and adverse medical events during this period were recorded.

Pain was documented by visual analog scale (VAS) on a scale from 0 to 10. Score of 0 meant absence of pain and 10 meant agonising unbearable pain that the patient can imagine. Pain scores were recorded pre-operatively, 48 h from surgery and at 3- and 6-month follow-up.

Continuous data were reported as mean (SD), while categorical data were reported as numbers (%). All comparisons were unpaired, and all test of significance were two-tailed. Continuous variables with normal or skewed distribution were analysed using Mann–Whitney U test and student's t test, respectively. Categorical variables were compared using Fisher's exact test or Chi-square test. All p values are two-tailed. Variables that showed p value of ≤ 0.05 were considered to be significant. Pearson correlation analysis was computed to assess the relation between TBL and variables such as age, body weight, duration of surgery, intraoperative blood loss, area of wound, diabetes, hypertension and obesity, and for this,

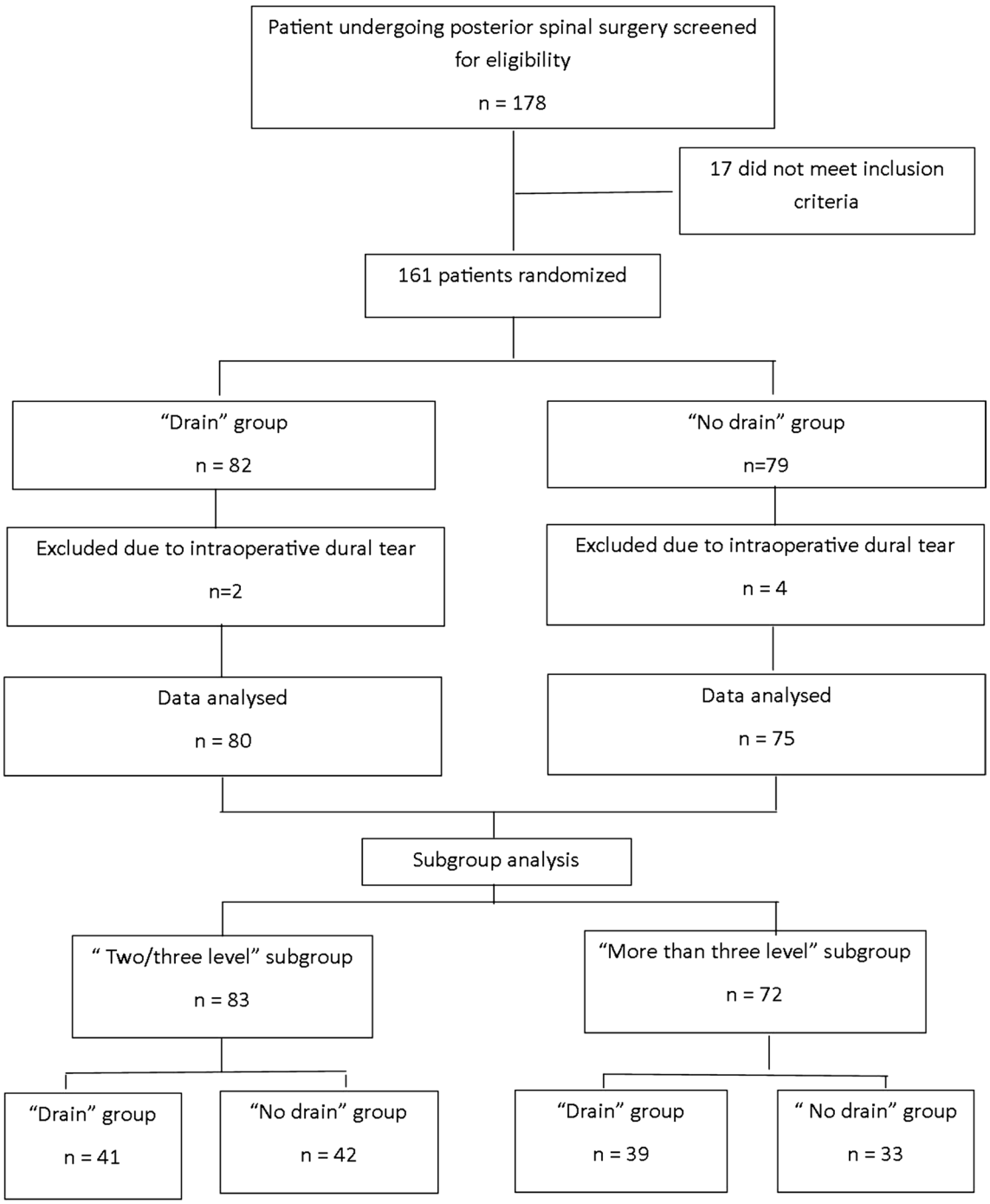


Fig. 1 Flow diagram showing the enrolment of patients, allocation of treatment and completion of the study

statistical significance was accepted at 0.01 level. Statistical analysis was performed using MedCalc v 15.8 (MedCalc Software, Ostend, Belgium).

Table 1 Comparison of demographic and clinical characteristics between drain and no-drain groups

Parameter	Drain ($n=80$)	No drain ($n=75$)	p value
Age, mean ± SD (years)*	48.4 ± 16.6	47.9 ± 16.6	0.619
Gender, male (%)**	33 (41.3%)	31 (41.3%)	1.000
Weight, mean ± SD*	78.9 ± 20.5	75.4 ± 20.5	0.569
Hypertension, *n* (%)**	36 (45%)	40 (53.3%)	0.336
Diabetes, *n* (%)**	5 (6.3%)	3 (4%)	0.720
Obesity, *n* (%)**	24 (30%)	17 (22.7%)	0.363

*By Mann–Whitney U test

**By Fisher's exact test

Table 2 Comparison of aetiologies for which spinal surgery was performed between drain and no-drain groups

Diagnosis	Drain ($n=80$)	No drain ($n=75$)	p value
Trauma, *n* (%)*	12 (15%)	11 (14.7%)	1.000
Spinal canal stenosis, *n* (%)*	34 (42.5%)	37 (49%)	0.423
Spondylolisthesis, *n* (%)*	5 (6.3%)	7 (9.3%)	0.555
Spinal deformity (scoliosis, kyphosis), *n* (%)*	28 (35%)	19 (25.3%)	0.223
Spinal tumour, *n* (%)*	1 (1.2%)	1 (1.7%)	1.000

*By Fisher's exact test

Results

Both "drain" and "no-drain" groups were comparable with regard to demographic and clinical characteristics of the patients enrolled (Table 1) and the nature of spinal surgeries performed (Table 2). The "drain" group had longer duration of surgeries and larger area of surgical wounds (length of the incision multiplied by the depth of the wound, both in millimetres), which was statistically significant (Table 3). Intraoperative blood loss in both groups was comparable (Table 3).

The total blood loss (primary outcome) was significantly lower in "no-drain" group (Table 4). The need of post-operative aspirations and the volume drained during such aspirations were significantly higher in "no-drain" group (Table 4). These aspirations were needed from third to eighth day of surgery. "Drain" group has significantly higher number of post-operative transfusions with regard to both the number of patients requiring transfusion and the volume of blood consumed (Table 4). The duration of hospital stay was comparable between both groups (Table 4).

We attempted subgroup analysis by dividing patients into surgery involving "two/three levels" ($n=83$) and "more than three levels" ($n=72$). All results with regard to primary and secondary outcomes were equally applicable to both subgroups (except that none of the patients needed post-operative blood transfusion in "two/three level" group) (Table 5).

Table 3 Comparison of intraoperative characteristics between drain and no-drain groups

Parameter	Drain ($n=80$)	No drain ($n=75$)	p value
Duration of surgery, mean ± SD (min)*	145.6 ± 59.0	124.6 ± 55.6	0.012**
Intraoperative blood loss, mean ± SD (ml)*	276.3 ± 166.8	250.5 ± 196.1	0.083
Area of wound, mean ± SD (mm^2)*	10,850 ± 6202.5	9118.7 ± 7063.6	0.001**

*By Mann–Whitney U test

**Significant p value

Table 4 Comparison of primary and secondary outcomes between "drain" and "no-drain" groups

Parameter	Drain ($n=80$)	No drain ($n=75$)	p value
Total blood loss, mean ± SD (ml)*	716 ± 312.97	377.9 ± 295.72	< 0.0001***
Number of post-operative aspirations**	42	87	0.0004***
Volume drained during post-operative aspirations, mean ± SD (ml)*	37.9 ± 138.4	127.3 ± 162.8	0.0001***
Post-operative drainage, mean ± SD (ml)*	439.8 ± 213.53	127.3 ± 162.8	< 0.0001***
Number of patients requiring blood transfusion in the group, *n* (%)**	8 (10%)	1 (0.01%)	0.0345***
Volume of blood transfusion used in the group, mean ± SD (ml per patient)*	285 ± 81.76	3.1 ± 0	0.027***
Complications	Superficial inflammation—1	Superficial inflammation—1	No meaningful analysis possible
Admission days, mean ± SD*	11 ± 3.8	10.2 ± 2.9	0.5118

*Mann–Whitney U test

**Fisher's exact test

***Significant p value

Table 5 Subgroup analysis with patients who had "two/three level" and "more than three level" surgeries with respect to primary and secondary outcomes

Subgroup	Two/three level surgery ($n=83$)			More than three level surgery ($n=72$)		
Parameter	Drain ($n=41$)	No drain ($n=42$)	p value	Drain ($n=39$)	No drain ($n=33$)	p value
Total blood loss, mean ± SD (ml)*	548.8 ± 173.3	228.3 ± 203.8	< 0.0001**	891.8 ± 327.3	568.2 ± 286.9	0.0002***
Number of post-operative aspirations**	0	21	0.0013**	42	66	0.0013***
Volume drained during post-operative aspirations, mean ± SD (ml)*	0	57.1 ± 117.1	0.0014**	77.7 ± 122.3	216.7 ± 170.3	0.0001***
Post-operative drainage, mean ± SD (ml)*	341.5 ± 114.4	57.1 ± 117.2	< 0.0001**	291.1 ± 243.5	216.7 ± 170.3	< 0.0001***
Number of patients requiring blood transfusion in the group, n (%)**	0 (0%)	0 (0%)	–	8 (20.5%)	1 (3.0%)	0.031***
Volume of blood transfusion used in the group, mean ± SD (ml per patient)*	0 (0%)	0 (0%)	–	58.4 ± 123	7 ± 40	0.027***
Complications	0 (0%)	0 (0%)	–	Superficial inflammation—1	Superficial inflammation—1	No meaningful analysis possible
Admission days, mean ± SD*	9.5 ± 2.5	9.3 ± 2.2	0.600	12.5 ± 5.3	11.4 ± 3.3	0.586

*Mann–Whitney U test

**Fisher's exact test

***Significant p value

Table 6 Comparison of pain scores between "drain" and "no-drain" groups at pre-defined intervals

		SD	p value*
Pain score pre-operatively (mean)			
Drain	7	0.9278	0.3849
No drain	7.1	0.9772	
Pain at 48 h from surgery (mean)			
Drain	5.5	0.8268	0.7332
No drain	5.5	0.8745	
Pain at 3-month follow-up (mean)			
Drain	3.3	0.7563	0.0006**
No drain	3.7	0.6319	
Pain at 6-month follow-up (mean)			
Drain	3.2	0.8065	0.4473
No drain	3.1	0.6967	

*By t test

**Significant p value

Pain by VAS was comparable pre-operatively and at 48 h from surgery between "drain" and "no-drain" groups, the "drain" group fared slightly better with regard to pain at 3 months post-operatively (3.3 ± 0.74 vs 3.7 ± 0.63, p—0.0006). However, average pain scores returned to comparable levels at 6 months from surgery (Table 6).

Table 7 Correlation between variables and total blood loss (TBL) by Pearson's correlation analysis

Variables	Pearson r value	p value
Age	−0.096	0.235
Body weight	−0.161	0.045
Duration of surgery	0.643	< 0.0001*
Intraoperative blood loss	0.739	< 0.0001*
Area of wound	0.547	< 0.0001*
Diabetes	−0.006	0.943
Hypertension	−0.161	0.046
Obesity	−0.068	0.399

*Significant p value

Overall one patient each in "drain" and "no-drain" group under the "more than three level" subgroup had superficial wound inflammation that was detected after discharge from hospital when the patients reviewed for removal of sutures. Cultures from them did not yield any growth. Both of them responded to conservative measures that involved regular dressings and a week-long course of oral antibiotic. However, no meaningful statistical analysis was possible as their incidence was extremely low. None of the aspirate samples sent for microbiological examination yielded any growth.

Our correlation analysis revealed that there was a significant positive correlation between TBL and variables such as duration of surgery ($p < 0.0001$, Pearson $r = 0.643$), intraoperative blood loss ($p < 0.0001$, Pearson $r = 0.739$) and area of wound ($p < 0.0001$, Pearson $r = 0.547$). TBL was not influenced by variables like age of the patient, body weight and presence of comorbidities like diabetes, hypertension and obesity (Table 7).

Discussion

Though use of drain after spine surgery is extremely common, its effectiveness remains controversial [20]. Due to emerging evidence suggesting increased risk of post-operative complications with drain, some surgeons have given up using drains [21]. A nation-wide survey in Australia revealed that spine surgeons continue to use drain even without conclusive evidence regarding its benefit [22]. The study by Diab et al. [18] asked 50 spine surgeons whether they used drain: 36 did and 14 did not. Half of those who used did so out of habit. In the background of no scientific evidence for the practice of using drain and the paucity of studies addressing this subject, we undertook this study [13–15].

Our study revealed that drain definitely increases post-operative blood loss and blood transfusions regardless of the number of spinal levels operated upon. Except for one case, in each of superficial wound inflammation in either group, we did not encounter any complication. We acknowledge that the duration of surgery and area of surgical wound were marginally higher in the "drain" group than in "no-drain" group. Both parameters imply that the extent of surgery could have been slightly more in the "drain" group that could have acted as a confounder and the result must be interpreted with this small caution. Also, we compared only the length and depth of the surgical wound. There is a third dimension, which is the lateral extent of the dissection that could not be documented.

Our study comes out with benefits and risks of abandoning the use of drain in spinal surgeries involving more than one level. The study suggests that abandoning the practice of drain will definitely reduce the amount of perioperative blood loss and the need for post-operative blood transfusion without increasing wound complications. We did close monitoring of the surgical wounds, and if the surgical site developed any collection, we aspirated them.

Among patients in "two/three level" subgroup, none of the patients in "drain" category needed post-operative aspirations, whereas 21 patients in the "no-drain" category needed aspirations. In the "more than three level"" subgroup, both "drain" and "no-drain" group needed post-operative aspirations. But the number of aspirations needed and the volume of aspirate were significantly higher in the "no-drain" group. It essentially means that drain does not eliminate the possibility of post-operative collection, especially in the "more than three level" subgroup.

At the same time, patients with "no drain" need closer monitoring of their wounds to prevent complications as unaddressed collection can lead on to wound dehiscence and infection. We recommend that wounds must be monitored for soakage for at least 10 days from surgery (as we needed to aspirate till eighth day from surgery) and be inspected whenever there is any soakage. We acknowledge that every dressing and aspiration theoretically increase the chances of infection and patients must be cautioned in this direction, even though none of our patient had significant infection. Even though all our patients tolerated aspirations well, this can cause anxiety and concern in patients and must be borne in mind when adopting a "no-drain" strategy.

To our knowledge, there are only two RCTs in the literature comparable to our study [10, 12].Brown and Brookfield [10] studied patients ($n = 83$, 42 with drain and 41 without drain) with more than single-level spinal surgery like that of ours. No complications arose in either group with the only difference being a higher temperature of patients in the "no-drain" group during the first post-operative day. They concluded the use of drains "does not alter clinical course" in lumbar surgery and its use "should be left to the discretion of the surgeon". The other study differed from ours in that they studied only patients ($n = 30$, 18 with drain and 12 without drain) who underwent scoliosis surgery [12]. Three of the 12 patients without drain developed wound complications. None of the drained group developed any complication. The study concluded the use of drains could reduce the incidence of post-operative complications. In contrast to one study favouring and the other not supporting the use of drain, our findings gives risks and benefits. Perioperative blood loss and transfusions were found comparable among the two groups in the other two studies, as opposed to our study [10, 12]. This calls for the need of more single- and multi-centre trials on the subject in the future.

Compared to other studies our sample size was the highest, powered even for subgroup analysis of surgeries involving "two/three levels" and "more than three levels" [10, 12]. Thus our conclusions are valid for all spinal surgeries involving more than one motion segment. Meticulous inpatient follow-up for wound complications (with prompt intervention) and availability of the required follow-up for all patients are obvious merits of the study.

We acknowledge the following limitations. Blinding was not feasible as the intervention is obvious. Blood loss was measured based on visible losses during surgery, in drain and during aspirations. We did not include hidden blood losses based on haematocrit drop to preserve external validity of our findings. This could have been potentially inaccurate, which is a major limitation of the study. Between the

two available RCTs on "drain" versus "no drain" in patients undergoing single-level disc surgery [11, 23], one did not favour the use of drain [11], whereas the other did [23]. The basis of recommending drain in the latter study was increased rate and size of extradural haematoma formation in "no-drain" group as seen on MRI study performed on first post-operative day [23]. However, the significance of this radiological finding remains unknown in terms of long-term clinical outcome. We did not use any imaging modality to assess extradural haematoma in our cases, mostly because of the presence of metallic implants in many of our cases that may interfere with accuracy of measurements. As haematoma can theoretically contribute to fibrosis and affect final outcome, it needs to be seen on long term how both groups perform in terms of pain and function. Our sample size was not powered enough to pick-up the difference in the incidence of complications which were infrequent in our series. A detailed cost-analysis (consumables for drain, blood transfusion, etc.) could have enriched the study, but we could not employ.

Our study suggests the benefits of abandoning the practice of closed suction drain in posterior spinal surgeries involving more than one motion segment, based on increased perioperative losses and need for blood transfusion associated with the use of drain. However, the study also alerts the possibility of increased soakage, need for more frequent dressings and post-operative aspiration of surgical wounds with possibility of introducing infection from outside. Thus our study could not conclusively recommend against the practice of using closed surgical drains. We believe that the risks and benefits must be weighed on a case to case basis, involving patient counselling regarding the risks and benefits and an informed choice be taken.

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Compliance with ethical standards

Conflict of interest All authors certify that they have no conflict of interests.

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