Are Lumbar Drains Necessary After Outpatient Lumbar Interbody Fusion Using Less Exposure Surgery Techniques?

KR Chin[1, 2, 3], FJR Pencle[4], AM O'Neill[4], KJ Conklin[4], MJ McGarry[3], JA Seale[3]

ABSTRACT

Objective: *The use of postoperative drains for elective spine surgery has not been justified. In transitioning to the outpatient setting, there may be concerns for haematoma formation in same day procedures. The purpose of the study is to evaluate the outcomes of lumbar spine surgery with no drains in the outpatient setting compared to the inpatient setting.*

Methods: *The medical records of prospectively collected data for 170 patients who had single-level posterior lumbar interbody fusion (PLIF) were retrospectively reviewed. Two equal cohort groups of 85 patients were assessed, inpatients in which PLIF with drains was performed in the hospital setting, and outpatients with PLIF without drains was performed in the ambulatory surgery centre (ASC).*

Results: *Eighty-nine males and 81 females, overall mean age 53.7 ± 1.4 years and mean body mass index (BMI) 28.3 ± 0.6. Inpatient pre-operative oswestry disability index (ODI) score improved from 50.3 ± 1.8 to 36.3 ± 1.3 at final follow-up,* $p < 0.001$*. Outpatient pre-operative ODI means reduced from 46.2 ± 1.6 to 29.2 ± 0.9,* $p < 0.001$*. There were significant improvement in ODI scores in Group 2 compared to Group 1,* $p = 0.001$*. Mean operative times difference of 62 minutes revealed a statistically significant decrease in the outpatient group,* $p = 0.003$*. Four patients (5%) developed postoperative haematoma in the Group with drains, this was significantly more than patients without drains,* $p = 0.04$*.*

Conclusion: *Single-level PLIF can be safely done in the outpatient setting without the use of drains. This can be attributed to operative time reduction, less exposure surgery techniques and the use of haemostatic agents.*

Keywords: Ambulatory surgery centre, less exposure surgery, low back pain, outcomes, outpatient, posterior lumbar interbody fusions, postoperative drains, spine surgery

¿Son los drenajes lumbares necesarios después de una fusión intersomática lumbar ambulatoria con técnicas de cirugía de menos exposición?

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RESUMEN

Objetivo: *No se ha justificado el uso de drenaje postoperatorio para la cirugía electiva de columna vertebral. En la transición al escenario ambulatorio puede haber preocupación por la formación de hematomas en los procedimientos del mismo día. El propósito del estudio es evaluar los resultados de la cirugía de la columna lumbar sin drenajes en el contexto ambulatorio, en comparación con el escenario intrahospitalario.*

Métodos: *Se revisaron retrospectivamente las historias clínicas de los datos recogidos prospectiva-*

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mente de 170 pacientes que tuvieron fusión lumbar intersomática posterior (FLIP) de un solo nivel. Se evaluaron dos grupos iguales de cohorte de 85 pacientes, pacientes hospitalizados a quienes se les realizó FLIP con drenajes en el contexto intrahospitalario y pacientes ambulatorios a los cuales se les realizó FLIP sin drenajes en el centro de cirugía ambulatoria (CCA).

Resultados: *Ochenta y nueve varones y 81 hembras, edad media general 53.7 ± 1.4 años e índice de masa corporal medio (IMC) 28.3 ± 0.6. La puntuación del índice de discapacidad de Owestry 9 (IDO) en la fase preoperatoria intrahospitalaria, mejoró de 50.3 ± 1.8 a 36.3 ± 1.3 en el seguimiento final,* p *< 0.001. Las medias del IDO en la fase preoperatoria ambulatoria se redujeron de 46.2 ± 1.6 a 29.2 ± 0.9,* p *< 0.001. Hubo una mejoría significativa en las puntuaciones del IDO en el Grupo 2 comparado con el Grupo 1,* p *= 0.001. La diferencia media de 62 minutos de los tiempos operatorios, reveló una disminución estadísticamente significativa en el grupo de pacientes ambulatorios,* p *= 0.003. Cuatro pacientes (5%) desarrollaron hematomas postoperatorios en el grupo con drenajes, significativamente mayor que en el caso de los pacientes sin drenajes,* p *= 0.04.*

Conclusión: *El procedimiento PLIF de un solo nivel puede realizarse con seguridad en un contexto ambulatorio sin el uso de drenajes. Esto puede atribuirse a la reducción del tiempo operatorio, las técnicas de cirugía de menos exposición, y el uso de agentes hemostáticos.*

Palabras claves: centro de cirugía ambulatoria, cirugía de menos exposición, dolor lumbar, ambulatorio, resultados, fusión lumbar intersomática posterior, drenaje postoperatorio, cirugía de columna

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INTRODUCTION

The use of postoperative drains after major surgery, especially thoracoabdominal, is well established (1, 2). Despite known complications of prolonged use, such as local pain and infection, the benefits of their use are believed to outweigh their risks, particularly after emergency surgery (3). Notwithstanding the widespread use of postoperative lumbar drains by orthopaedic spine surgeons, there exists, a paucity of evidence to justify this practice. Research however, does suggest that the use of drains after elective posterior lumbar surgery does not affect clinical outcome. The practice is viewed as counter-intuitive by some authors, by potentially providing a conduit for micro-organisms and ultimately contaminating an otherwise clean wound (2, 4).

Further, a drain may prolong blood loss and increase the need for blood transfusion in the postoperative period. Proponents for the use of suction drains after elective single-level posterior lumbar interbody fusion (PLIF) defend the practice with the goal of preventing the development of postoperative haematoma, infection and faster wound healing. A cochrane review, however, found that the need for reinforcement of dressings and the incidence of bruising increased in patients without drains postoperatively (5). This same study also concluded that the evidence is not sufficient enough to justify the routine use of postoperative closed suction drainage after orthopaedic surgery.

In order to transition from inpatient to outpatient surgery, innovative new techniques and instruments are needed. The utilization of lumbar drains has to be evaluated. Parameters to be assessed include, estimated blood loss (EBL), surgeon time and the use of haemostatic agents. The purpose of the study is to evaluate the outcomes of lumbar spine surgery with no drains in the outpatient setting compared to the inpatient setting.

SUBJECTS AND METHODS

The medical records of prospectively collected data of 170 patients from multiple institutions who underwent single-level PLIF were reviewed. Two groups were created, Group 1 in which PLIF with drains was performed in the inpatient hospital setting and Group 2 where PLIF without drains was performed in the outpatient ambulatory surgery centre (ASC). All operations were performed by a single surgeon, who was experienced in performing PLIF in academic and private hospitals as if it were in an outpatient setting, prior to commencing in an outpatient setting. Data regarding these groups were collected from medical records and operative notes. Institutional review board approval was obtained for this study from our institution as part of a cohort of patient with fixation techniques being performed.

Indications for surgery included chronic disabling low back-pain or leg pain secondary to stenosis from degenerative disc or facet disease with or without low-grade spondylolisthesis, central canal or foraminal stenosis. All included patients had failed a minimum of six months of conservative therapy which comprised of anti-inflammatory medications, physical therapy and radiofrequency rhizotomies for patients with suspected facet-mediated axial back-pain. Informed patient preference and surgeon discretion prompted the decision to operate via a posterior approach.

Inclusion criteria used in this study (6)

Body mass index </= 42. (6–8)

- All patients with chronic medical illnesses must be stable and be cleared by their family practitioner and/or specialist where applicable (6, 7, 9).
- Patients with a history of heart disease must be cleared through cardiologist evaluation including, echocardio-

gram and/or stress test (6, 7, 9).
- Low-to-moderate anaesthesia risks [ASA criteria1 to 3] (6, 7, 10).

Exclusion criteria used in this study
- Patients with a history of malignant tumours, spinal infections, congenital diseases.
- Patients with history of major acute traumas, major deformities (severe scoliosis, ankylosing spondylitis *etc*) and pulmonary embolism.
- Patients who had previous lumbar spine surgery.

Demographic data collected included, age, gender, body mass index (BMI), smoking status, type of instrumentation in order to minimize confounders and bias (Table 1).

Table 1: Demographic data of sample population

Demographic	Hospital (Inpatient) PLIF	ASC (Outpatient) PLIF
Mean age (years)	57	49
Male	46	43
Female	39	42
Mean BMI (kg/m^2)	27.6	29.4
Smoker	33	38
Non-smoker	52	47

BMI: Body mass index; ASC: ambulatory surgery centre; PLIF: posterior lumbar interbody fusion

Outcome measures documented were pre-operative and postoperative visual analogue scale (VAS) scores, oswestry disability indices (ODI) for lower back-pain also at two years postoperatively. Estimated blood loss, mean operative times in both groups, use of haemostatic agents, surgical technique and the presence or absence of a postoperative haematoma or infection requiring reoperation for treatment, were also evaluated.

Less exposure surgery technique

Positioning

Patient was placed prone on Wilson frame. To facilitate the decompression, the Wilson frame was flexed to open the distance between the spinous processes and lamina. The C-arm was draped and brought into the field. An anteroposterior (AP) and lateral fluoroscopic image was taken to confirm appropriate alignment of the spine as well as to view all necessary anatomical landmarks.

Incision

Under fluoroscopic guidance, a 22 G spinal needle was used to localize the correct operative level and define the angle of dissection (11). A midline longitudinal skin incision approximately 1.5 inches long was made slightly biased to the upper operative level.

Exposure

Vertical incisions were made adjacent to the spinous processes along an avascular plane using electrocautery. Subperiosteal dissection was performed to strip the muscular attachments and avoid any traversing blood vessels in a vertical fashion rather than by a fanning motion and to avoid creating a dead space. Dissection should be carried down the spinous process of the superior level to the lateral pars and ending just proximal to the facet joint capsule. The caudal level of dissection can end once the inferior facet is exposed and the lateral pars can be palpated with a Penfield 4.

Decompression

High speed Burr and Kerrison ronguers were used to perform hemilaminotomies and partial fasciotomies in a limited manner so as to preserve as much as the lamina as possible. Bone wax was placed at all bony defects for haemostasis. The proximal attachment of the ligamentum flavum was detached using a straight curette. The curette was worked from the proximal attachment to the lateral attachment along the medial facet. Finally, the caudal attachment of the ligamentum flavum on inferior level was detached. This creates a U-shaped flap of ligamentum flavum that is still connected medially. This U-shaped piece of ligamentum flavum was used to protect the nerve root and dura and also function as a natural retractor exposing the disc. Another advantage of preserving the ligamentum is that it is able to fall back over the disc and create a "roof" over the discectomy and control the bleeding from the disc space. The ligamentum flavum was only removed in cases of severe spinal stenosis or Grade 2 spondylolisthesis. Epidural veins were located and bipolar cauterization was performed to avoid bleeding. In the event that there was any epidural bleeding, we used bipolar cauterization and applied haemostatic agents with thrombin and gelatin.

Discectomy

Discectomy is performed using various instruments. The endplates were prepared and an adequately sized interbody device PLIF was measured, packed and placed into the disc space. The above steps were repeated on the contralateral side.

Instrumented fusions

Posterior instrumentation was placed for fusion using either cortical pedicle screws or transfacet pedicle screws. Irrigation was performed and adequate haemostasis achieved with the aid of haemostatic agents and bipolar electrocautery (Fig. 3). Closure was performed in layers.

Statistical analysis

Statistical analysis was performed using SPSS v22 (IBM corporation, New York, USA). An independent sample student *t*-test was used to compare groups for continuous data and Chi-square used for categorical data. Continuous data com-parisons were expressed as means with standard error.

Tests were considered significant if $p < 0.05$. Power analyses was performed based on outcomes of haematoma incidence and prior study to achieve a power of 0.8 and alpha of 0.05, a total sample size of 75 patients was necessary (12, 13).

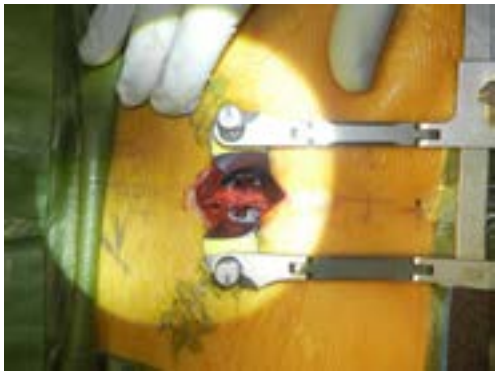

Fig. 3: Intra-operative photograph demonstrating adequate haemostasis.

RESULTS

A total of 170 patients was evaluated and two cohort groups analysed. Group 1 comprised of 85 patients with PLIF with drains in the hospital setting and Group 2 consisted of 85 patients with PLIF without drains in the ASC. Females represented 48% of patients overall, however, there was no difference in gender between groups, $p = 0.645$. Overall, age and BMI was 53.7 ± 1.4 years and 28.3 ± 0.6, respectively. Mean age of Group 1 was 57 ± 2.0 and Group 2 was 49 ± 2.0 ($p = 0.166$). Mean body mass index for Groups 1 and 2 were 27.6 ± 0.8 and 29.4 ± 0.9, respectively, $p = 0.68$. Positive smoking history was 42% overall, with no significance between groups, $p = 0.437$.

Functional outcomes

Group 1 mean pre-operative visual analogue scale (VAS) back-pain scores improved from 7.6 ± 0.2 to 2.6 ± 0.1 at final follow-up, $p < 0.001$. Mean pre-operative ODI score improved from 50.3 ± 1.8 to 36.3 ± 1.3 at final follow-up, $p < 0.001$. In Group 2, the pre-operative VAS score improved from 8.1 ± 0.2 to 2.5 ± 0.2, $p < 0.001$. Pre-operative ODI means reduced from 46.2 ± 1.6 to 29.2 ± 0.9, $p < 0.001$. Statistical comparison of final follow-up outcomes between Groups 1 and 2 showed no statistical difference in VAS scores ($p = 0.5$) but a significant improvement in ODI scores in Group 2 compared to Group 1, $p = 0.001$. Outcome scores are summarized in (Figs. 1 and 2).

The analysis showed Group 1 mean operative times of 206 ± 4 minutes and Group 2 mean operative times of 142 ± 7 minutes. This difference of 62 minutes revealed a statistically significant decrease in the outpatient group, $p = 0.003$. There was no significance for estimated blood loss, Group 1 resulting with 139 ± 14 mL lost and Group 2 with 119 ± 16 mL ($p = 0.143$).

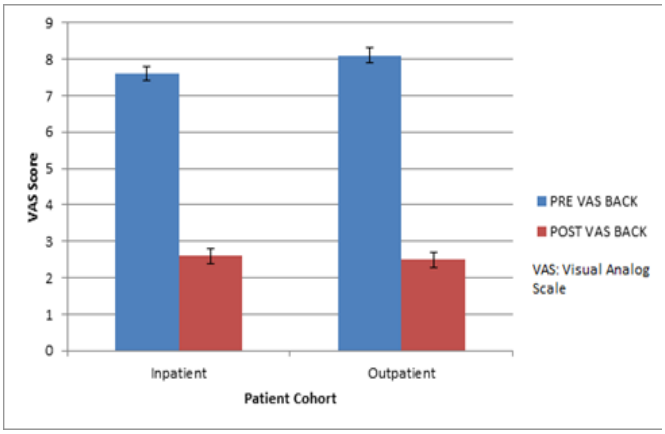

Fig. 1: Bar graph illustrating inpatient and outpatient visual analogue scale scores.

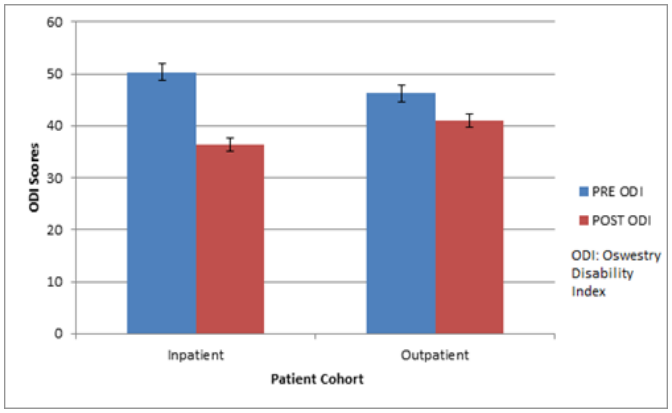

Fig. 2: Bar graph illustrating inpatient and outpatient Oswestry disability indices scores.

Follow-up

Postoperative follow-up was performed within 14 days and at six weeks to assess clinically for haematoma or fluid formation. Radiographs were performed within the first 14 days to confirm instrumentation and check for any signs of haematoma or fluid collection (Fig. 4A/B).

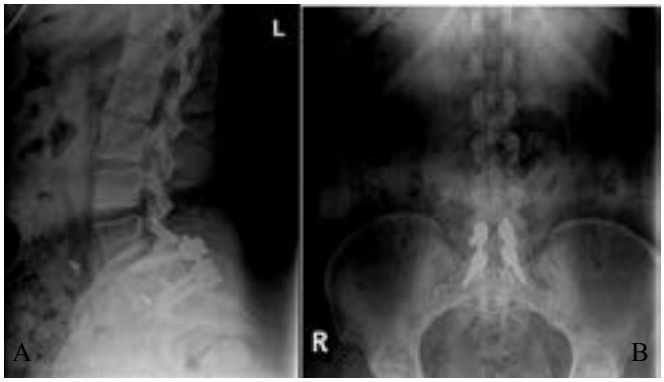

Fig. 4: Postoperative X-rays showing instrumentation A. Lateral and B. Anteroposterior

Sagittal and axial computed tomography (CT) were evaluated by the authors (KRC, FJRP, and JAS) to look for graft subsidence, implant failure and status of fusion. Fusion was defined as the absence of radiolucencies and evidence of bridging trabecular bone within the fusion area (Fig. 5A/B). Fusion was achieved in 96% (164) of patients. No bony fusion was noted in five inpatients and implant failure was noted in one outpatient.

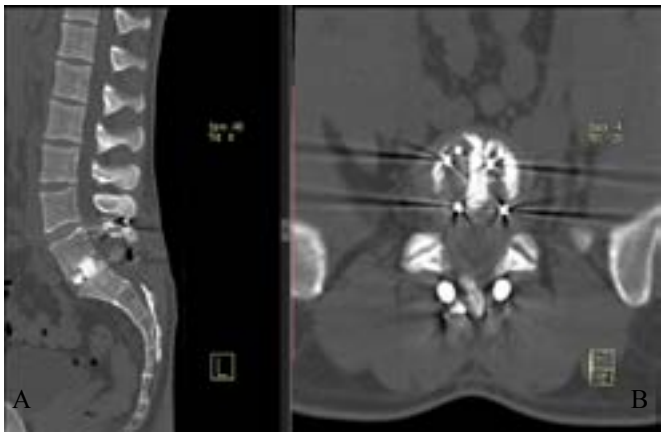

Fig. 5: Computed tomography demonstrating fusion in A. Sagittal and B. Axial films.

Complications

Overall complication rates were higher in Group 1 for both neurological and non-neurological complications defined as new onset complaints (14). The most common complication overall observed in both groups was dermatome numbness (12% and 7% in Groups 1 and 2, respectively). Specifically looking at the incidence of postoperative wound collections: four patients (5%) developed postoperative haematoma in the group with drains while in hospital; however, no patients in the ASC (patients without drains) developed haematomas. surgery was required for wound drainage and irrigation for one patient secondary to persistent pain. Chi-square testing demonstrated a significant difference, $p = 0.04$. There were no infections noted in either group.

DISCUSSION

This study aimed to assess the procedural outcomes of single-level PLIF performed in both the hospital and surgery centre settings. Overall, a statistically significant improvement in ODI scores was observed for those in the outpatient *versus* in-patient setting. Although the difference in VAS scores between both groups was not significant, surgical time was statistically lower for the outpatient group. In the subset of patients without drains, there was no incidence of postoperative haematoma or infection. This was significantly less than patients with drains in the hospital setting. In the hospital setting, the patients who had haematoma formation had full laminectomies for decompression, thus, creating additional dead space and excessive bleeding from bone ends. To reduce this factor in the outpatient setting hemilaminectomy was performed reducing operative time and bleeding. Factors which therefore contribute to a decrease haematoma formation, include performing hemilaminectomy for decompression technique, reduced operative time and use of haemostatic agents to achieve adequate haemostasis.

The use of intra-operative drainage devices for the theoretical protection against potential haematoma development, infection and wound breakdown postoperatively, has been long debated in the literature (1, 15). In our patient population, there was not a significant increase in the potential complications from the absence of a spinal drain. Furthermore, no patients developed complications requiring further surgical management, related to the presence of a drain. Brown *et al* (16), conducted a prospective, randomized study involving: 83 patients who underwent extensive lumbar spine surgery; in which 42 had closed suction lumbar drainage and 41 had no drains.

Their conclusions were that the clinical course was not altered with or without the use of a lumbar drain, haematoma formation and infection was not impacted by the presence or absence of a drain, and that their use in the lumbar spine should be solely based on surgeon discretion (16). The major potential complication of foregoing a drain is the potential development of an infection within a haematoma that develops postoperatively and which may require reoperation. This study is limited in determining the rate of haematoma or non-infected fluid collection development in the postoperative period and the relation to drain placement, due to the need of a much larger sample size to determine a change in incidence of a rare event. Other limitations include the retrospective nature of this series and the fact that it is a single-surgeon investigation.

In a large multicentre retrospective study of 450 patients undergoing multilevel surgery for the treatment of adolescent idiopathic scoliosis, 324 patients had drains and 126 did not have drains. Fifty surgeons participated, 36 used drains and 14 did not. A practice pattern survey was conducted in which those who used drains gave their reasons for use in their patients. Most surgeons did not give a reason other than habit (18), others were concerned about excessive bleeding (10), presence of an open vertebral canal (9) after an osteotomy (6), in a revision case and an international normalization ratio (INR) greater than 1.5 (17). Similarly, the present study also concluded that the use of drains did not affect complication rate.

The association of postoperative complications and drain placement in single-level lumbar spine surgery has been investigated also. Scuderi conducted a study on single-level laminectomy and found that the use of closed suction drain in single-level laminectomy was not associated with increased risk of epidural haematoma and subsequent neural compromise (18). Kanayama and colleagues, retrospectively reviewed 560 patients who underwent single-level lumbar decompression surgery, in which 298 patients received drains up until 2003 and 262 did not after they discontinued the practice. They evaluated the incidence of infection and epidural

haematoma development postoperatively and like the majority of studies, found no association with the use or absence of a drain (12).

Independent risk factors associated with the development of postoperative spinal epidural haematomas have been investigated. Awad and colleagues reviewed a total of 14 932 patients who underwent spinal surgeries. Their results revealed the following statistically significant risk factors, $p < 0.03$: operative levels > 5, haemoglobin level of < 10 g/dL, intra-operative blood loss of > 1L and INR > 2 within the first 48 hours postoperatively (19).

This study, although a retrospective comparative review, underscores similar findings demonstrated throughout the literature. Single-level posterior lumbar decompression and interbody fusion did not show any risk associated with foregoing drain placement. A limitation noted by the author is the use of postoperative X-rays to assess for haematoma or fluid formation to aid clinical examination, ideally magnetic resonance imaging (MRI) should be used. Authors also note if a full laminectomy is performed for appropriate indication, a drain may be required. This paper looked at the safety and practice of not using lumbar drains in the outpatient setting and further multi-centre, multi-surgeon, multilevel prospective and randomized studies should be conducted to accurately elucidate any potential risks associated with, not leaving a drain in patients undergoing outpatient posterior lumbar decompression and interbody fusion.

CONCLUSION

This study has demonstrated that the use of postoperative drains for single-level lumbar fusion in elective spine surgery and the outpatient setting is not necessary. Modification of decompression technique, reduction in operative time and the use of haemostatic agents are factors to be considered which contributed to this fact.

AUTHORS' NOTE

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REFERENCES

1. Cobb JP. Why use drains? J Bone Joint Surg Br 1990; **72:** 993–5.
2. Gaines RJ, Dunbar RP. The use of surgical drains in orthopaedics. Orthopaedics 2008; **31:** 702–5.
3. Chandratreya A, Giannikas K, Livesley P. To drain or not drain: literature versus practice. J R Coll Surg Edinb 1998; **43:** 404–6.
4. Cerise EJ, Pierce WA, Diamond DL. Abdominal drains: their role as a source of infection following splenectomy. Ann Surg 1970; **171:** 764–9.
5. Parker MJ, Livingstone V, Clifton R, McKee A. Closed suction surgical wound drainage after orthopaedic surgery. Cochrane Database Syst Rev 2007; **18:** CD001825.
6. Chin KR, Pencle FJ, Coombs AV, Packer CF, Hothem EA, Seale JA. Eligibility of outpatient spine surgery candidates in a single private practice. Clin Spine Surg 2017; **30:** E1352–8.
7. Chin KR, Coombs AV, Seale JA. Feasibility and patient-reported outcomes after outpatient single-level instrumented posterior lumbar interbody fusion in a surgery centre: preliminary results in 16 patients. Spine (Phila Pa 1976). 2015; **40:** E36–42.
8. Hofer RE, Kai T, Decker PA, Warner DO. Obesity as a risk factor for unanticipated admissions after ambulatory surgery. Mayo Clin Proc 2008; **83:** 908–16.
9. Fleisher LA, Fleischmann KE, Auerbach AD, Barnason SA, Beckman JA, Bozkurt B et al. 2014 ACC/AHA guideline on perioperative cardiovascular evaluation and management of patients undergoing noncardiac surgery: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. J Am Coll Cardiol 2014; **64:** e77–137.
10. Fu KM, Smith JS, Polly DW Jr, Ames CP, Berven SH, Perra JH et al. Correlation of higher preoperative American Society of Anesthesiology grade and increased morbidity and mortality rates in patients undergoing spine surgery. J Neurosurg Spine 2011; **14:** 470–4.
11. Chin KR, Pencle FJR, Kubik J, Coombs AV, Seale JA, Hothem EAH et al. Avoidance of wrong level surgery in the lumbar spine: Report 2015; **4:** 257.
12. Kanayama M, Oha F, Togawa D, Shigenobu K, Hashimoto T. Is closed-suction drainage necessary for single-level lumbar decompression?: review of 560 cases. Clin Orthop Relat Res 2010; **468:** 2690–4.
13. Carneiro AV. Estimating sample size in clinical studies: basic methodological principles. Rev Port Cardiol 2003; **22:** 1513–21.
14. Kardaun JW, White LR, Shaffer WO. Acute complications in patients with surgical treatment of lumbar herniated disc. J Spinal Disord 1990; **3:** 30–8.
15. Bean KJ. A history of surgical wound drainage: sump drains and closed wound suction devices. J Oper Room Res Inst 1983; **3:** 8–20. Epub 1983/03/01.
16. Brown MD, Brookfield KF. A randomized study of closed wound suc-tion drainage for extensive lumbar spine surgery. Spine (Phila Pa 1976). 2004; **29:** 1066–8.
17. Diab M, Smucny M, Dormans JP, Erickson MA, Ibrahim K, Lenke LG et al. Use and outcomes of wound drain in spinal fusion for adolescent idiopathic scoliosis. Spine (Phila Pa 1976). 2012; **37:** 966–73.
18. Scuderi GJ, Brusovanik GV, Fitzhenry LN, Vaccaro AR. Is wound drainage necessary after lumbar spinal fusion surgery? Med Sci Monit 2005; **11:** CR64–6.
19. Awad JN, Kebaish KM, Donigan J, Cohen DB, Kostuik JP. Analysis of the risk factors for the development of post-operative spinal epidural haematoma. J Bone Joint Surg Br 2005; **87:** 1248–52.