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“Does size matter?” A comparison of balloon-assisted less-invasive vs conventional retroperitoneal approach for anterior lumbar interbody fusion

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Abstract This is a case-series comparison of two approaches to anterior lumbar interbody fusion. A conventional open approach (COA) was compared with a balloon-assisted minimally invasive approach (BMI). Outcome measures included operating time, blood loss and complications. Secondary outcome measures included analgesia requirements, time to mobilization and inpatient stay. There were 17 females (7 COA, 10 BMI) and 18 males (9 COA and 9 BMI). Forty-five discs (21 COA, 24 BMI) in total were fused in

35 patients. There were significant differences (in favour of the BMI) in the overall operating time between the COA and the BMI, and the single level COA and the BMI. There was no inter-group difference in the PCA requirements either overall or between one or two-level operations. The less invasive approach did have a benefit in earlier mobilization of the single-level fusions.

Keywords Lumbar spine · Interbody fusion · Less invasive surgery · Balloon assisted

Introduction

One of the major developments in spine surgery within the past 10 years has been the development of novel approaches to the anterior thoracic and lumbar spine [2, 4, 7, 10]. The anterior lumbar spine can be accessed via retroperitoneal or trans-peritoneal routes. Conventionally, techniques tended to be through long incisions, which was necessary for safe visualization, retraction of tissues and to permit adequate illumination of the operative field.

Minimally invasive approaches to perform anterior lumbar interbody fusions (ALIF) are theoretically desirable to minimize surgical tissue damage, decrease morbidity, shorten the hospital stay, and therefore reduce overall costs. There have been recent reports of novel endoscopic or minimally open approaches. Endoscopic techniques have not found widespread acceptance, because they are technically demanding (often requiring the assistance of a laparoscopic surgeon), time-consuming and predominantly limited to L5/S1 pathology. The purpose of this study was to compare a Conventional Open Approach (COA) [6] with

a modification of the balloon-assisted endoscopic retroperitoneal gasless (BERG) approach [10]. The endoscope was not employed and the balloon was used to assist the retroperitoneal dissection. For the purpose of this article we termed this technique the balloon-assisted minimally invasive (BMI) approach.

Materials and methods

Thirty-five consecutive cases under the care of the senior author (M.P.G.) who had single- or double-level ALIF at University Hospital, Nottingham, between 1997 and 2000, were included in this study. The study is a review of all case records of relevant patients identified from the operative log maintained by the senior author. This was an independent evaluation by a research Fellow who had not been involved in these patients' care and not employed by the senior author.

All patients had disabling low back pain with no significant leg pain or radiculopathy. All had either failed or not achieved sufficient functional benefit from a vigorous non-operative spinal rehabilitation regimen.

Initial investigations included plain radiographs and MRI scans in every case. All patients had provocative discography of degenerate lumbar discs. All patients had one or more discograms that

Fig. 1 **a** Disassembled balloon dissector. Trocar, sheath and bellows in descending order. **b** Inflated balloon

Fig. 2 **a** A balloon-assisted minimally invasive approach incision with balloon dissector. **b** Balloon dissector inserted and gradual inflation with ballotment of loin

was positively concordant to pain. Only 2 ml of contrast per disc was injected and an essential pre-requisite for an adequate study was a control disc that produced no pain. The senior author performed all the procedures using the same discographic technique throughout this study period.

All patients underwent a posterior translaminal facet screw fixation [6] followed by an anterior lumbar interbody fusion (as a single-stage operation).

This study consisted of a consecutive series of open procedures followed by another case series using the BMI approach. In each case the surgery was either performed or supervised by the senior author. If not the senior author, the primary surgeon was a spinal fellow on a year's specialty training (usually after 6 years of general orthopaedic residency).

Surgical technique

All patients underwent posterior translaminal screw fixation with fusion of the facet joints in the prone position as the first part of the single-stage procedure. No concomitant postero-lateral fusion was performed for a single level operation. For a two-level fusion, concerns to minimize the pseudarthrosis rate meant that a postero-lateral fusion was carried out. Additional facet joint decortication and bone grafting was performed. The posterior operation was the same for both study groups.

For the COA the initial incision was paramedian, 10 cm in length. The anterior rectus sheath was divided longitudinally and the muscle retracted laterally to expose the posterior rectus sheath. The arcuate linea was identified, dissected free from the peritoneum and divided. If the exposure was inadequate, the inferior free border of the posterior rectus sheath was divided proximally. The peritoneum was reflected away from the abdominal wall with cottonoid pledgets and swabs. The reflection of the peritoneum extended laterally to the left and then routed medially over the psoas muscle. The peritoneal sac (and contents) were then pulled medially to expose the left iliac vessels or the bifurcation at the lumbo-sacral promontory. The left ilio-lumbar vein (where present) was identi-

fied early in the approach. It was ligated and divided to facilitate medial mobilization of the vessels at the L4/5 disc space.

At the L5/S1 space the median sacral vessels were ligated and divided. The vessels were retracted laterally with plastic-sheathed Steinmann pins placed in a quadrilateral configuration around the disc space and hammered into the vertebral bodies.

In the BMI approach a 3-cm left paramedian incision was made. Following opening of the anterior rectus sheath, the rectus muscle was retracted laterally. This limited incision allowed separation of the posterior rectus sheath from the peritoneum and was adequate space for insertion of a cottonoid pledget dissector to reflect the peritoneal sac from the abdominal wall. The created retroperitoneal funnel space allowed passage of the balloon dissector (Fig. 1) in an inferior and lateral direction (Fig. 2). Gradual inflation further dissected the peritoneum off the lateral wall of the abdomen and created an approximately 1-l-sized cavity. This cavity was further enlarged by insertion of retractor blades fixed to a commercial ring frame (Synframe, Stratec, Welwyn Garden City, UK; Fig. 3). Retraction of the blades expanded the initial incision to provide (in most instances) a 5-cm diameter aperture through which further dissection and isolation of the disc space could be accomplished (Fig. 4). The medial lip of the blade retractors were placed under the vessels thereby protecting them from injury.

In the case of the approach to L5/S1 ligation and division of the median sacral vessels then allowed lateral retraction of the iliac vessels to expose the lateral margins of the annulus. For the approach to L4/5 the lateral border of the external iliac vein was explored to determine the presence and (often variable) anatomy of the ascending lumbar vein. These tributaries were ligated and divided, as were the vertebral segmental vessels at L4. Only once these manoeuvres were complete was the iliac vein mobilized across the midline to expose the disc.

Once the disc was isolated total discectomy was performed. This study was part of a larger prospective, randomized comparison of femoral ring allograft vs titanium interbody spacer (Syncage, Stratec, Welwyn Garden City, UK). All patients in this article were included in that study. There was no significant difference in the distribution of the anterior implants between the two groups.

Fig. 3 Retraction system in place

Fig. 4 Operative view of L5/S1 disc. Retractor blades protecting vessels

Recorded outcome parameters in both the groups included intra-operative blood loss (including both anterior and posterior procedures), time of procedure, intra-operative complications, patient-controlled analgesia (PCA) requirement (measured in milliliters of morphine sulphate), time to mobilization and length of hospital stay. The calculated total operative time was from the time of first skin incision for the posterior procedure to the last stitch at conclusion of the ALIF. This included the theatre turnaround period after the posterior procedure during which the patient was re-positioned, re-draped and fresh instruments were brought. In the chart review it was difficult to distinguish the separate operative times for the anterior fusion and posterior stabilization. "Day to mobilization" was the postoperative day the patient took their first post-operative walk.

Thirty-five patients were included in this study. Sixteen patients underwent anterior fusion through the COA and 19 patients underwent the fusion through the BMI. There was no previous experience of the BMI.

The two groups were matched for age, sex and number of levels to be fused. There were 17 females (7 COA, 10 BMI) and 18 males (9 COA and 9 BMI; Table 1). Forty-five discs (21 COA, 24 BMI) in total were fused in 35 patients. The levels of the 21 discs fused by COA were L3/4 ($n=1$), L4/5 ($n=9$) and L5/S1 ($n=11$; Table 2). The levels of the 24 discs fused by the BMI were L4/5 ($n=7$) and L5/S1 ($n=17$). The average age of the patients undergoing the COA was 43.6 years (range 28–58 years) and for BMI 43.5 years (range 30–54 years).

Table 1 Groups matched by age and sex. COA conventional open approach, BMI balloon-assisted minimally invasive approach, PCA patient-controlled analgesia, NS not significant

	COA	BMI	<i>p</i> value
No. of patients	16	19	
Sex (M:F)	9:7	9:10	
Age (years; range)	43.6 (28–58)	43.5 (30–54)	NS
Blood loss (ml)	1102	518	NS
Operating time (min)	289	221	0.05
PCA requirements (mg)	71.8	75.1	NS
Time to mobilize (days)	3.5	2.2	0.02
Inpatient stay (days)	7.1	6.2	NS

Table 2 Groups matched by number of levels to be fused

	COA	BMI	<i>p</i> value
Single level			
Blood loss (ml)	613	414	NS
Operating time (min)	265	125	0.01
PCA requirements (mg)	60.0	51.7	NS
Time to mobilize (days)	3.9	2.1	0.01
Inpatient stay (days)	7.1	5.8	NS
Double level			
Blood loss (ml)	2325	810	NS
Operating time (min)	342	347	NS
PCA requirements (mg)	97.8	140.4	NS
Time to mobilize (days)	2.6	2.4	NS
Inpatient stay (days)	7.0	7.4	NS

Statistical analysis used the SPSS for Windows statistical package. Baseline characteristics were compared between treatment groups using χ^2 test for categorical variables and the Kruskal-Wallis test for continuous variables. A one-way ANOVA was used to compare the outcome variables.

Results

The results are given in Tables 1 and 2. The overall mean operating time for the COA was 289 min (range 100–480 min) and for the BMI was 221 min (range 90–390 min).

The mean total operating time for the single level COA was 265 min (range 120–480 min) and for the BMI was 175 min (range 90–240 min). The operating time for two level fusions by the COA was 342 min (range 180–420) and for the BMI was 347 min (range 265–390 min). There was statistically significant difference in the overall operating time between the COA and the BMI ($p=0.05$) and the single level COA and the BMI ($p=0.013$).

The mean overall blood loss for the COA was 1102 ml (range 150–5000 ml) and for the BMI 518 ml (range of 50–1320 ml). The mean blood loss for the single level COA was 612 ml (range 150–1000 ml) and for the BMI 414 ml (range 50–1320 ml). The blood loss for the two-level COA

was 2325 ml (range 600–5000 ml) and for the BMI was 810 ml (range 350–1300 ml).

The PCA requirement for overall COA was 71.8 ml (range 4–260 ml) and for the BMI 75.05 ml (range 1–265 ml). The PCA requirement for single level COA was 60 ml (range 2–210 ml) and for the single BMI 51.71 (range 1–110). The PCA requirement for the two-level COA group was 97.8 ml (range 24–260 ml) and for the two-level BMI 140.4 ml (range 50–265 ml).

The mean day to mobilization for the entire COA group was 3.5 days (range 2–10 days) and for the entire BMI group 2.2 days (range 1–3 days). For a single-level COA the average day to mobilization was 3.9 days (range 2–10 days) and for the single-level BMI 2.1 days (range 1–3 days). The average day to mobilization for a two-level COA was 2.6 days (range 2–4 days) and for the two-level BMI was 2.4 days (range 2–3 days). There was significant difference in mobilization between the entire BMI and the COA groups ($p=0.015$). There was a statistically significant difference in day to mobilization for the single-level fusions between the BMI and the COA ($p=0.009$).

The mean inpatient stay in hospital for the COA overall was 7.06 days (range 4–13 days) and for the BMI 6.21 days (range 4–9 days). The mean total stay in hospital for a single level COA was 7.09 days (range 4–13 days) and for the single BMI 5.8 days (range 4–9 days). The total stay in hospital for the two-level COA group was 7 days (range 6–9 days) and for the two-level BMI was 7.4 days (range 5–9 days).

Complications

The overall complications for COA were three vascular injuries and for the BMI there was one vascular injury and one superficial infection of the posterior wound. The complication for single-level COA was two vascular injuries and for the single-level BMI group one vascular injury. The complications for the two-level COA were one vascular injury and none for the two-level BMI. All the vascular injuries involved an approach to the L4/5 disc. Three injuries involved segmental vessels, these were easily controlled with titanium vascular clips and minimal extra blood loss. There was one significant vascular injury (two-level COA) involving a tear of the left common iliac vein that required formal suture repair. There were no postoperative sequelae related to this complication and the patient mobilized within 2 days. The wound infection settled with oral antibiotics. There was no incidence of post-operative ileus (defined as gastro-intestinal stasis requiring naso-gastric suction and prolonged intravenous fluids) in either series. There was no case of retrograde ejaculation. There was one case (one level L4/5 BMI) of a warm leg from division of the sympathetic chain. The symptoms settled after 2 years.

One patient (single-level COA) had significant back spasm and pain after surgery. This resulted in a signifi-

cantly delayed mobilization (10 days) and discharge from hospital.

The clinical and radiological outcomes of the fusions form an ongoing part of a prospective study in our institution and these outcomes are not included in this study.

Discussion

Burns was the first to describe anterior lumbar interbody fusion (ALIF) in 1933 [3]. The key technical points of an anterior fusion are [12]:

1. Adequate exposure to allow safe visualization of the anterior portion of the inter-vertebral disc space
2. Complete excision of the disc material from the disc space
3. Removal of the cartilaginous portion of the vertebral end plates to bleeding bone of the vertebral end plate
4. Placing the graft material under sufficient compression on conclusion of the procedure to preclude displacement from the disc space

Any approach to the anterior lumbar spine should provide adequate surgical access for achieving the above surgical steps. Conventional approaches to the anterior lumbar spine include both the trans-peritoneal and the retroperitoneal routes either by open or endoscopic means. The disadvantages of the endoscopic procedure include a long learning curve (or the necessary assistance of a laparoscopic surgeon), the difficulty of the approach to L4/5 and the problems of maintaining a pneumo-peritoneum (requiring special instruments and trocars). The open procedure is arguably easier, due to it being more familiar to the orthopaedist, easier isolation of the intervertebral disc space (especially at L4/5) and use of normal instruments and implants in a “gasless” operation [11]. The disadvantage of the open procedure is the longer incision and the morbidity associated with a bigger wound [11]. The balloon-assisted dissection that we have used in our series (BMI) has been reported in other studies such as the balloon-assisted endoscopic retro-peritoneal gasless approach (BERG) [10]. Video-assisted techniques do permit the assistants and the rest of the surgical team to see the operation. Its use, however, is not an essential pre-requisite for the operation and the equipment is expensive. Insertion of an endoscope into the midline wound obstructs the surgeon’s view and we do not believe that a separate incision to insert the endoscope is justified.

Conventional open approaches, however, do have to be of adequate size to allow initial insertion of instruments to dissect peritoneum from the abdominal wall. Boos et al. [2] describe an endoscopically assisted technique to accomplish the initial extraperitoneal dissection. The study was complicated by peritoneal perforations that made further CO₂ insufflation difficult. We believe that this endoscopic elaboration confers no additional benefit. The ini-

tial extra-peritoneal dissection can be accomplished under direct vision through a modest incision. Although the peritoneum may be a flimsy structure (particularly in females) and may be firmly adherent to the arcuate line, the necessary dissection of the peritoneum off the arcuate line can be readily achieved by conventional means. If peritoneal tears occur, they are easily repaired and these repairs present no problems without CO₂ insufflation. In obese individuals, the establishment of a sufficient size retroperitoneal space (especially infero-laterally) can present difficulties. The balloon dissector used for our minimally invasive method accomplished this manoeuvre providing adequate access for further retro-peritoneal dissection through a limited incision. We believe that the additional cost of the balloon dissector (183 Euros at the time of this study) was justified as this facilitated the approach in this difficult group and there were additional benefits in time saving (with the single-level fusions).

Once the retroperitoneal space is created, the next challenge is to pull the peritoneal sac medially and maintain its retraction thereby exposing the spine and overlying vascular structures. Mayer [5] describes a microsurgical technique utilizing a special retractor. We do not find the notion of two separate approaches for L4/5 and L5/S1 appealing but support the notion of a special retraction system. The advantages of such a system include adapted blades that can retract and protect the vascular structures, capability of adjustment in a stepwise fashion to develop the exposure and illumination cables can be integrated into the system. It is difficult to envisage how hand-held retractors can achieve the same aims or how surgical assistance can be effective when visualization is limited through small incisions.

There was no statistical difference in the blood loss between the two approaches. This was an expected finding as the posterior operation was the same in both groups and the expected blood losses from the anterior fusion are minimal in the absence of vascular injury. There was a smaller incidence of vascular complications in the BMI. This attests to the adequate visualization through this less invasive approach. There were proportionally more vascular injuries in the COA group. This, in all probability, reflects the greater number of L4/5 ALIF in this group. Most experienced spine surgeons will acknowledge more vascular complications at this level compared with L5/S1. This is due to the necessary medial retraction of the great vessels to adequately expose the disc and the need to deal with the often highly variable anatomy of the ascending ilio-lumbar vein. The incidence of vascular complications would appear higher than other reported series [2, 11]. This may represent different reporting criteria (we included all vascular injuries that required control with either clips or sutures). In contrast to the common practice in the United States, no vascular or additional access surgeons assisted in these surgeries and all approaches were initiated by the spinal surgeons who were orthopaedists by training. Fur-

thermore, approximately half of all the operations were offered to the spinal fellow for training purposes supervised by the senior author.

The operative time for the single-level BMI was significantly less as compared with the COA. There was a greater number of L5/S1 ALIF in the BMI group, demonstrating the advantages of BMI at this level. The relative ease with which the lumbosacral junction was exposed, and the good retraction and visualization provided by a modern retraction system, all contribute to the faster operating time despite a considerably smaller incision.

The problem with a retrospective review of two consecutive case series is inability to eliminate confounding variables. The two groups were broadly matched in terms of the age, sex, numbers of fusion levels and implants used. It could be argued that the longer operating time and higher vascular complication rate in the COA group was a "learning" curve phenomenon. This would account for the differences when compared with BMI. We believe that this is not the case. The senior author already had considerable experience of anterior spinal approaches prior to inception of the randomized, prospective study of which these patients formed part. The fact that the BMI experience represented a learning curve is more likely. Despite this, there was still significant difference in certain parameters between the two groups. What is clear from our experience is that considerable familiarity with conventional open surgery is required before minimal-access approaches are attempted.

The advantages of the BMI appear less convincing for two-level fusions when compared with the COA. The total operating time was longer, compared with single-level fusions, and this was due to the more extensive posterior procedure and need to deal with the ilio-lumbar vein. These additional factors probably negated the benefits offered by the balloon dissector and ring retraction system.

Nonetheless, these times are comparable to those of other reports of ALIF (assuming that the average time for our two-level translamina screw fusion and turnaround time was of the order of 90 min) [2, 9].

There was no inter-group difference in the PCA requirements either overall or between one or two-level operations. The majority of the PCA pumps were discontinued by 36 h post-operatively, by which time regular oral analgesia was better tolerated. In that initial period, it is the pain and discomfort of the posterior procedure that appears to be the major determinant of the PCA utilization. We did attempt to audit the oral analgesic requirement leading up to discharge from hospital. There was no discernible difference in the quantity of oral analgesics used between BMI and COA. This was due to the unit protocol of regular prescription of paracetamol and non-steroidal anti-inflammatory medication regardless of the patient's pain level.

The less invasive approach does have a benefit in earlier mobilization of the single-level fusions. Less posterior

muscle dissection, smaller anterior incisions (with less retraction of rectus abdominis muscle) resulted in a greater willingness of the patient to get out of bed and co-operate with the physical therapists. Anecdotal reports from patients reflected the view that the smaller incision implied less major surgery that some individuals found more reassuring than those with anterior larger wounds. Although our unit has some experience with laparoscopic BAK fusions, we did not compare these results with that reported series as the senior author was not involved with that study (O'Dowd, unpublished data). The operating times in this report are substantially less than the Nottingham laparoscopic BAK series. It is the senior author's view that this series of mini-ALIF confirms the view of others that laparoscopic lumbar fusion is a more demanding technique, takes longer to perform and is associated with a greater complication rate [9].

The time to mobilization analysis was significantly hampered by the patient with single-level COA who had prolonged back spasm and bed rest. If this case is excluded, the time to mobilization in the more extensive two-level surgery was longer when compared with the single-level fusions. In addition, there was no difference between BMI and COA for the double-level fusions. This most probably reflects the residual effect of the more extensive posterior operation and postero-lateral fusion. This is despite the fact that the two level BMI anterior incision is a size comparable to that used in a monosegmental fusion.

An aspect not explored in this study was the cosmesis of the BMI when compared with COA. At latest follow-up, all patients with BMI were pleased with the size and appearances of the healed wound. In the COA group there were two female patients that either had some sensitivity of the wound or were displeased with its appearance.

Conclusion

We used a technique that combines the advantages of open surgery and balloon-assisted dissection. Our results show that a minimally open technique with balloon-assisted dissection (and combined with modern retraction systems) to be equally, if not more effective, than COA for single-level fusions.

The results of this study indicate that a BMI allows easy performance of a single-level ALIF without additional hazard to the patient. We have been unable to prove that this minimally invasive approach is categorically superior to the COA in all outcome measures tested. We have been able to demonstrate that the overall comparison of BMI and COA operative time and time to mobilization is superior with the BMI. Furthermore, the BMI was not associated with an increased incidence of adverse events such as vascular injury. We recommend this approach for single-level anterior interbody fusion especially at L5/S1.

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