Anterior lumbar interbody fusion using rhBMP-2

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Malham and colleagues present a thorough review of their experience with the use of human recombinant bone morphogenetic protein–2 (rhBMP-2) for anterior lumbar interbody fusion surgery (ALIF). In addition to assessing the usual clinical outcomes measures, they specifically sought to determine the incidence of sexual dysfunction and/or retrograde ejaculation (RE) subsequent to these surgeries. Their cohort included 131 consecutive patients treated over a 3-year period. Of these, 67 males (51%) were included. Their study involved predominantly young (mean age 45 years), healthy patients with relatively few comorbidities.

Their results were generally excellent with statistically significant improvements determined in both disease-specific and general patient-reported outcomes measures. They found improvements according to the visual analog scale for both back and leg, the 36-Item Short Form Health Survey, and Oswestry Disability Index. As the great majority of patients (117/131) had ALIF surgery at L5–S1 in a young, healthy cohort, these good results are expected. Noteworthy was the authors’ attempt to delineate the incidence of RE and/or sexual dysfunctions. They had patients complete an RE/sexual dysfunction questionnaire both before and after surgery. Of 67 male patients treated, only 1 patient developed RE postoperatively. These results, especially for a group for which RE was specifically sought, are superb.

The authors are to be commended for numerous aspects of this study. They had a 96.9% fusion rate at 12 months. Most importantly, fusions were confirmed by CT scans that demonstrated bridging trabecular bone, which is the most difficult test for proving successful bony arthrodesis. Another important aspect was that the fusion determination was completed by an independent radiologist. In addition, the patients’ clinical results were assessed by independent physicians who were not involved with the surgical procedures. While the authors reported an overall complication rate of 19% (6% major and 13% minor), which is relatively high for this type of procedure, it is likely that the prospective search for complications is responsible as it is well known that this methodology identifies more complications than retrospective analyses. Most importantly, the authors specifically looked for evidence of sexual dysfunction and did not find it. This is at odds with other studies, which have identified appreciably higher rates of RE. The authors hypothesized that using a low dose of rhBMP-2 (only 3.2 mg/case) and placing the chemically active substance within the cage and not around it contributed to the low rate identified. They further suggest that RE is more likely the result of approach-related complications, rather than rhBMP-2 usage, which is responsible for the RE reported in some other studies. This hypothesis seems reasonable based on the authors’ results.

There are 3 areas where concerns arise and are not completely addressed in this paper. The RE/sexual dysfunction questionnaire appears relatively subjective. The authors do not state whether this outcomes measure has been validated for the purposes it is utilized in this study. While the authors report that the questionnaire was approved by a urologist from another institution, it is not clear whether this method has been validated. The authors also report a median follow-up of 12 months rather than a mean follow-up, which is more traditionally reported. Lastly, the authors describe the use of cell-saver strategies; however, the mean blood loss was only 115 ml and it appears that this was an unnecessary addition to the surgery as the blood recovered did not appear to have been returned.

Despite some relatively minor areas where this paper could be improved, the authors have thoroughly assessed their patients and report excellent outcomes. They did not find difficulties with sexual dysfunction following the use of rhBMP-2 in ALIF surgeries and they are to be commended for submitting an article, which adds to the growing body of knowledge on this topic.

Disclosure

The author reports no conflict of interest.

Reference

Response

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The RE/sexual dysfunction questionnaire utilized in this study was originally developed in 2006 by Hägg et al. for the postoperative assessment of sexual function following anterior lumbar surgery. This questionnaire was then adapted by Berg et al. to include a preoperative assessment for comparing sexual function after total disc replacement and posterior lumbar fusion. In our study we simplified the questionnaire by Berg et al. to focus on pre- and postoperative sexual dysfunction and in particular RE. Although this questionnaire has not been validated, it has been approved by an independent urologist and similar versions of this questionnaire have been published in 2 peer-reviewed journals. In our opinion, this questionnaire is superior to a single nonspecific question about sexual function in the postoperative review and we continue to use it as part of normal clinical practice.

The mean follow-up was 14.6 months; however, the median of 12 months was used in this study as the follow-up time data were skewed to the right (positive skew). This was due to the fact that most of the values were concentrated to the left of the mean, with the majority of patients having 6–12 months of follow-up (70.2%) rather than 12–24 months (29.8%). The skewness of the data was 0.553 and since this was greater than 2 times the standard error (0.212), the data were significantly skewed and hence the median provided a more accurate representation of our follow-up time.

We are aware that the use of cell-saver strategies is not universal in the anterior approach for spine surgery. However, we recognize the potential for significant hemorrhage and use a safety-first approach. Vascular injury is a potential complication in anterior exposures, where a major venous injury may result in liters of blood being lost in a short period of time. In Australia the cost of the cell saver is $658 (including cell-saver kit and autotransfusionist), which is fully reimbursed by the health insurance provider. When it comes to the use of cell-saver strategies, we prefer to hope for the best and plan for the worst.

References


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