

Original Article

Costs and frequency of "off-label" use of INFUSE for spinal fusions at one institution in 2010

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Abstract

Background: INFUSE, bone morphogenetic protein-2 combined with bovine Type I collagen in the lumbar tapered fusion device (LT Cage), is used to promote anterior lumbar interbody fusion (ALIF). In spinal surgery, INFUSE is only Federal Drug Administration (FDA) approved for this "on-label" use. While the efficacy and possible complications due to INFUSE have been debated, we know less about the costs and frequency of "on-label" versus "off-label" use of INFUSE to perform spinal fusions.

Methods: At one institution, we determined the costs (with overhead) and frequency of utilizing INFUSE "on-label" and "off-label" in performing spinal fusions during 2010.

Results: During 2010, 177 spinal fusions utilized INFUSE. Ninety-six percent, or 170 of 177 spinal fusions, utilized INFUSE in an "off-label" capacity at a cost of \$4,547,822. Only 4%, or seven of 177 cases, utilized INFUSE in an "on-label" capacity (ALIF); the total cost was \$296,419.

Conclusions: In 2010, at one institution, 96% of the spinal fusions utilized INFUSE in an "off-label" capacity (cost \$4,547,822), while only 4% were performed "on-label" (cost \$296,4194).

Key Words: INFUSE, spinal fusion, lumbar, cervical, thoracic, surgery, off-label

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Quick Response Code:**INTRODUCTION**

INFUSE (Medtronic, Memphis, TN, USA), a genetically engineered human bone morphogenetic protein-2, is utilized to perform both "on-label" and "off-label" spinal fusions. INFUSE, combined with a bovine Type I collagen carrier, and placed in a lumbar tapered fusion device (LT Cage), together constitute an "on-label" device approved by the Federal Drug Administration (FDA) for anterior lumbar interbody fusion (ALIF). Although we are all "aware" that INFUSE is frequently utilized in an "off-

label" capacity (not FDA approved) to perform other types of spinal fusions, here we quantify the costs and frequency of such "off-label" use at one institution in 2010.

MATERIALS AND METHODS

In 2010, INFUSE was used in an "on-label" or "off-label" capacity in 177 spinal fusions at one institution. Patients averaged 53 years of age (range, 19–85 years), and included 84 females and 93 males. Of note,

20.9% of the patients were over 65 years old. Surgical procedures included anterior, posterior or 360-degree cervical, thoracic and/or lumbar fusions (with/without decompression).

RESULTS

Of the 177 spinal fusions that utilized INFUSE, it was used “on-label” to perform seven ALIF. It was utilized “off-label” in the remaining 170 fusions. The “off-label” cervical fusions included seven operations from three operative categories [Table 1]. The “off-label” thoracic/lumbar fusions utilizing INFUSE included 163 operations from five operative categories [Table 1]. Most of the operations (156 cases) fell into three thoracic and/or lumbar categories: 59 posterior lumbar interbody fusions, 59 posterolateral thoracic/lumbar fusions and 38 transforaminal lumbar interbody fusions.

INFUSE was utilized “off-label” in 96% of the cases (170 of 177 patients) at a cost of \$4,547,822, whereas it was utilized “on-label” in only 4% of the cases (seven of 177 patients) at a cost of \$296,419. A total of 244 INFUSE packages were utilized in 177 cases for an average of 1.38 packages/case (range 1–4). The average cost of INFUSE per operation was \$26,752.

Second operations, not necessarily directly attributable to INFUSE, occurred in 32 (18.8%) of 170 patients undergoing “off-label” spinal fusions [Table 1]. Two of

seven “on-label” ALIF utilizing INFUSE also required secondary surgery.

DISCUSSION

We examined the use of INFUSE to perform spinal fusions in one institution during 1 year. Although INFUSE is only “marketed” by the company for “on-label” use, we found at our institution that 170 (96%) of 177 cases were performed “off-label” at a cost of \$4,547,822. In fact, only seven (4%) of 177 cases were performed “on label” for ALIF alone, at a cost of \$296,419. Of note, the average cost of INFUSE was \$26,752 per operation, while the average range of costs for alternative bone graft supplements (e.g., demineralized bone matrix and Beta TriCalcium Phosphate [Vitoss: OrthoVita, Malvern, PA, USA]) per operation would range from \$2,672 to \$4,000 (with overhead).

Although we cannot directly link the requirement for second spinal operations to the use of INFUSE in this study, other studies have done so.^[1-6] In particular, these studies have suggested that INFUSE leads to higher rates of hematomas/seromas, neurological deficits, soft-tissue swelling, ectopic bone formation, and vertebral osteolysis. The reoperation rate of 18.2% in the current study was larger than that reported in most of these studies.

Future cost-benefit analyses comparing INFUSE to less-expensive bone graft expanders are warranted for both “on-label” and “off-label” use.

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Table 1: Categories of "off-label" spinal fusions utilizing INFUSE at one institution in 2010

Operative categories	Number of First operations	Number of Re-operations	% Re-operations per category
Cervical operations			
Anterior Cervical discectomy/Fusion	2	0	0
Posterior Cervical fusion	4	0	0
360 Anterior/Posterior Cervical fusion	1	1	100
Thoracic/lumbar operations			
360 Anterior/Posterior Thoracic/Lumbar Fusion*	6	0	0
Extreme lateral Interbody fusion	1	1	100
Posterior Lumbar interbody fusion	59	12	20.3
Thoracic/Lumbar Laminectomy/Fusion	59	17	28.8
Transforaminal Interbody lumbar fusion	38	1	2.6

*With/without laminectomy/decompressions