BMJ Open Retrospective cohort study of usage patterns of epidural injections for spinal pain in the US fee-for-service Medicare population from 2000 to 2014

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ABSTRACT

Objective: To assess the usage patterns of epidural injections for chronic spinal pain in the fee-for-service (FFS) Medicare population from 2000 to 2014 in the USA.

Design: A retrospective cohort.

Methods: The descriptive analysis of the administrative database from Centers for Medicare and Medicaid Services (CMS) Physician/Supplier Procedure Summary (PSPS) master data from 2000 to 2014 was performed. The guidance from Strengthening the Reporting of Observational studies in Epidemiology (STROBE) was applied. Analysis included multiple variables based on the procedures, specialties and geography.

Results: Overall epidural injections increased 99% per 100 000 Medicare beneficiaries with an annual increase of 5% from 2000 to 2014. Lumbar interlaminar and caudal epidural injections constituted 36.2% of all epidural injections, with an overall decrease of 2% and an annual decrease of 0.2% per 100 000 Medicare beneficiaries. However, lumbosacral transforaminal epidural injections increased 609% with an annual increase of 15% from 2000 to 2014 per 100 000 Medicare population.

Conclusions: Usage of epidural injections increased from 2000 to 2014, with a decline thereafter. However, an escalating growth has been seen for lumbosacral transforaminal epidural injections despite numerous reports of complications and regulations to curb the usage of transforaminal epidural injections.

INTRODUCTION

The reports of neurological complications from epidural injections have taken centre stage in the USA^{1–7} and in other parts of the world over the years.⁸ Even though the basis for such alarm and subsequent regulatory atmosphere has been criticised,^{4–7} the explosive increase of numerous modalities to manage spinal pain including epidural injections and the economic impact have provided ammunition for such an atmosphere.^{9–18} Reports from the US Burden of Disease

Strengths and limitations of this study

- This assessment of usage patterns of epidural injections has been conducted to describe the characteristics of all types of epidural injections in managing chronic spinal pain in the fee-for-service (FFS) Medicare population in the USA from 2000 to 2014.
- The strengths of this assessment include use of 100% FFS Medicare population including those above and below 65 years of age.
- One of the limitations is that the study is restricted to only the Medicare population and patients with Medicare Advantage plans have not been included which constitute between 20% and 30% of the population.
- Additionally, while these results can be generalised to a great extent, caution must be exercised since in other population groups the usage might be materially different.

Collaborators¹⁹ and from other parts of the world^{20–21} have shown spinal pain occupying three of the five top categories of disability. In addition, the prevalence of chronic impairing low back pain has increased in one report 162% from 1992 to 2006, increasing from 3.9% to 10.2%.²² Further, multiple assessments also have shown the chronicity of spinal pain long after its onset.^{23–24} The evidence of increasing burden of disease and disability across the globe coupled with increasing numbers of treatments have created an unacceptable situation with economic, social and healthcare impact. Further complicating this circumstance is the widely debated issues of efficacy of these interventions.^{24–40}

The statistics show that epidural injections, including percutaneous adhesiolysis procedures, are the most commonly performed procedures in managing spinal pain among interventional techniques, varying from 58.6% in 2000 to 45.2% in 2014 of all

interventional techniques.¹⁵ The usage of epidural procedures, excluding percutaneous adhesiolysis, showed an overall increase of 165% or 96% per 100 000 fee-for-service (FFS) Medicare beneficiaries with an annual increase of 7.2% or 4.9% from 2000 to 2014¹⁵ showing a slight decrease compared to 2000 to 2013, from a rate of 105.6% to an annual increase of 5.7%. Interlaminar epidural injections have increased at a slower pace. Among the epidural injections, continuous epidural injections with catheterisation and neurolytic epidural procedures have not been used in managing chronic spinal pain. Manchikanti *et al.*^{11–14} in assessing Medicare FFS population in the USA from 2000 to 2013, showed an increase of 119% for cervical and thoracic interlaminar epidural injections and 11% for lumbosacral interlaminar and caudal epidural injections per 100 000 Medicare population with an annual increase of 6.2% or 0.8%, respectively. Contrasting these milder increases, they determined an explosive increase of 577% for lumbosacral transforaminal epidural injections and an 84% increase of cervical and thoracic transforaminal epidural injections per 100 000 Medicare population with an annual increase of 15.8% and 4.8%, respectively, during the same period.^{11 12 14} Thus, the use of epidural injections has risen dramatically, despite discordant opinions of their effectiveness and their association with rare, but catastrophic complications.^{24–44}

This study is undertaken with an aim of assessing the usage patterns and patterns of use of epidural injections in Medicare FFS population in the USA with the analysis of data from 2000 to 2014.

METHODS

Approval by the Institutional Review Board (IRB) was not sought for this assessment as all analysis encompassed public use files (PUF) or non-identifiable data, which is non-attributable and non-confidential, available through the Centers for Medicare and Medicaid Services (CMS) database.⁴⁵ The study was performed using Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidance.⁴⁶

Study design

The study was designed to assess usage patterns of epidural injections, excluding continuous epidurals and neurolytic procedures, which constitute a small proportion used for chronic management, in the FFS Medicare population in the USA from 2000 to 2014.

Setting

National database of specialty usage data files from CMS, USA, FFS Medicare.⁴⁵

Participants

Participants included the FFS Medicare recipients from 2000 to 2014.

For analysis, the current procedure codes for epidural injections were used. The CPT codes used included epidural codes CPT 62310, 62311 and transforaminal epidural codes CPT 64479, 64480, 64483 and 64484. These codes were identified for years 2000 to 2014. Subsequently, usage data were assessed based on the place of service, either the facility which included ambulatory surgery centres and hospital outpatient departments (HOPDs), or a non-facility setting—the office. The data are calculated for overall services for each technique, and the rate of services for 100 000 Medicare beneficiaries, and also based on the specialty.

Variables

Multiple characteristics are assessed in this evaluation of the Medicare population and increase in the Medicare population from 2000 to 2014, usage of epidural procedures in the cervical, thoracic, lumbar and sacral spine. Additional characteristics assessed included various specialty designations and the settings in which the procedures were performed.

The description of various specialties was as follows: multiple specialties representing interventional pain physicians including interventional pain management –09, pain medicine –72, anaesthesiology –05, physical medicine and rehabilitation –25, neurology –13, psychiatry –26 were described as interventional pain management. Surgical specialties included orthopaedic surgery –20, general surgery –17 and neurosurgery –14. Radiologic specialties included diagnostic radiology –30 and –94 interventional radiology. All other physicians were grouped into a separate group (general physicians), and all other non-physician providers were considered as other providers.

Data sources

The data were obtained from the CMS physician supplier procedure summary master data from 2000 through 2014.⁴⁵ These data provide all FFS Medicare participants below the age of 65 and above the age of 65 receiving epidural procedures.

Measures

Allowed services were calculated from services submitted minus services denied and services with zero payments.

Allowed services were assessed for each procedure, and rates were calculated based on Medicare beneficiaries for the corresponding year and are reported as procedures per 100 000 Medicare beneficiaries.

Bias

The study was conducted with the internal resources of the primary author's practice without any external funding, either from industry or elsewhere. The data were purchased from CMS by the American Society of Interventional Pain Physicians (ASIPP). CMS's 100% data set consists of usage by CPT code with modifier usage (as an additional procedure or bilateral procedure), specialty codes, place of service, Medicare carrier

number, total services and charges submitted, allowed and denied, and amount paid.

Study size

The study size is large with inclusion of all patients under Medicare FFS undergoing epidural procedures for spinal pain from 2000 to 2014.

Data compilation

The data were compiled using Microsoft Access 2003 and Microsoft Excel 2003 (Microsoft, Redmond, Washington, USA).

RESULTS

Participants

Participants included the FFS Medicare recipients from 2000 to 2014.

Descriptive data

Table 1 illustrates the characteristics of Medicare beneficiaries as well as the epidural injections provided to them. Medicare beneficiaries increased 35% from 2000 to 2014 compared to an increase of 99% in the rate (per 100 000 Medicare beneficiaries) of epidural injections with an annual increase of 5% compared to a 2.2% annual increase in the number of Medicare beneficiaries which is 2.6 times the increase of the population rate.

Usage characteristics

Table 2 and figure 1 illustrate the usage characteristics of epidural injections in the Medicare population from 2000 to 2014. Overall epidural injections increased 99% per 100 000 Medicare beneficiaries with an annual increase of 5%. However, lumbosacral interlaminar and caudal epidural injections (CPT 62311) decreased 2% per 100 000 Medicare beneficiaries with a 0.2% annual decrease compared to an increase of 104% per 100 000 beneficiaries and a 5.2% annual increase for cervical/thoracic interlaminar epidural injections (CPT 62310). In contrast, lumbosacral transforaminal epidural injections (CPT 64483 and 64484) increased 609% per 100 000 population with an annual increase of 15% and cervical/thoracic transforaminal epidural injections (CPT 64479 and 64480) increased 93% with an annual increase of 4.8%. Thus, all the decrease in usage of interlaminar epidural injections were compensated by increases of transforaminal epidural injections in the lumbar spine. In addition, cervical and thoracic transforaminal epidural injections have been decreasing from 2011 to 2013 but have shown an increase in 2014. Using the number of patient episodes providing the services, lumbar/sacral interlaminar or caudal epidural injections (CPT 62311) decreased at a rate of -2% from 2000 to 2014, whereas the rate of usage in 2014 was 815 858 services with 1525 per 100 000 Medicare FFS population with a decrease of 12.2% from the previous year and the decreases observed from 2006 through 2014. In

addition, the number of patient episodes with transforaminal epidural injections (CPT 64483) were slightly less with 763 793 services with 1428 per 100 000 Medicare population, with an increase of 15% from 2000 to 2014, with decreases observed in 2 years with 4.0% decrease in 2012 and 5.1% in 2013 with an increase of 4.7% in 2014. In 2000, 1560 patients per 100 000 Medicare population received lumbar and caudal epidural injections, whereas 214 received lumbar transforaminal epidural injections. These numbers decreased for interlaminar epidural injections from 1560 to 1525, whereas lumbar transforaminal epidural injections increased from 214 to 1428 per 100 000 Medicare population.

As shown in figure 2, the proportion of epidural injections of all interventional techniques performed reduced 57% to 45% from 2000 to 2014.

Specialty characteristics

Online supplementary appendices 1 and 2 illustrate the usage of epidural injections by various specialties. In the group of interventional pain management, including anaesthesiology, interventional pain management, pain medicine, physical medicine and rehabilitation, neurology and psychiatry, the rate of increase was 113% per 100 000 Medicare beneficiaries with an overall increase of 99% from 2000 to 2014. However, among these groups, physical medicine and rehabilitation showed an overall increase of 672% and 472% per 100 000 Medicare beneficiaries. Radiology, consisting of interventional radiology and diagnostic radiology, also showed an increasing rate of 167% per 100 000 Medicare beneficiaries from 2000 to 2014. Surgical specialties, including neurosurgery, orthopaedic surgery and general surgery, showed an increase of 58% from 2000 to 2014.

Site of service characteristics

Epidural injections are provided in multiple settings including HOPDs, ambulatory surgical centres (ASCs) and in physician's offices (in-office). There has been a significant shift over the years in epidural injections based on the location of the procedure's performance. In 2002, HOPD services constituted 54.3%, with ASCs providing 19.9% of the service, and in-office providing 25.8%. By 2014, the HOPD share decreased to 29.4%, the ASC share increased to 27.7% and the in-office share dramatically increased to 42.9% as shown in online supplementary appendices 3 and 4.

Main results

- Epidural injections increased 99% per 100 000 Medicare beneficiaries with an annual increase of 5% in FFS Medicare beneficiaries from 2000 to 2014. Lumbar interlaminar and caudal epidural injections constituted 36.2% of all epidural injections, with an overall decrease of 2% and an annual decrease of 0.2% per 100 000 Medicare beneficiaries.
- Lumbosacral transforaminal epidural injections increased 609% with an annual increase of 15% from 2000 to 2014 per 100 000 Medicare population.

Table 1 Characteristics of Medicare beneficiaries and epidural procedures excluding percutaneous adhesiolysis, continuous epidurals and neurolytic epidurals.

	US population		Medicare beneficiaries				Epidural services*				
	Total population (,000)	≥65 years (,000)		Number (,000)	Per cent to US population	≥65 years (,000) (%)	<65 years (,000) %	Services*	Per cent of change from previous year	Per 100 000 Medicare FFS enrollees	Per cent of change from previous year
		Number	Per cent								
Y2000	282 172	35 077	12.4	39 632	14.0	34 262 (86.5%)	5370 (13.5%)	839 474 (80%)	NA	2118	–
Y2001	285 040	35 332	12.4	40 045	14.0	34 478 (86.1%)	5567 (13.9%)	989 034 (78%)	17.8	2470	16.6
Y2002	288 369	35 605	12.3	40 503	14.0	34 698 (85.7%)	5805 (14.3%)	1 172 248 (74%)	18.5	2894	17.2
Y2003	290 211	35 952	12.4	41 126	14.2	35 050 (85.2%)	6078 (14.8%)	1 342 829 (71%)	14.6	3265	12.8
Y2004	292 892	36 302	12.4	41 729	14.2	35 328 (84.7%)	6402 (15.3%)	1 611 887 (65%)	20.0	3863	18.3
Y2005	295 561	36 752	12.4	42 496	14.4	35 777 (84.2%)	6723 (15.8%)	1 747 771 (65%)	8.4	4113	6.5
Y2006	299 395	37 264	12.4	43 339	14.5	36 317 (83.8%)	7022 (16.2%)	1 844 182 (63%)	5.5	4255	3.5
Y2007	301 290	37 942	12.6	44 263	14.7	36 966 (83.5%)	7297 (16.5%)	1 915 227 (62%)	3.9	4327	1.7
Y2008	304 056	38 870	12.8	45 412	14.9	37 896 (83.4%)	7516 (16.6%)	2 017 132 (61%)	5.3	4442	2.7
Y2009	307 006	39 570	12.9	45 801	14.9	38 177 (83.4%)	7624 (16.6%)	2 112 511 (59%)	4.7	4612	3.8
Y2010	308 746	40 268	13.0	46 914	15.2	38 991 (83.1%)	7923 (16.9%)	2 205 307 (57%)	4.4	4701	1.9
Y2011	311 583	41 370	13.3	48 300	15.5	40 000 (82.8%)	8300 (17.2%)	2 289 213 (58%)	3.8	4740	0.8
Y2012	313 874	43 144	13.8	50 300	16.0	41 900 (83.3%)	8500 (16.9%)	2 304 993 (58%)	0.7	4582	–3.3
Y2013	316 129	44 704	14.1	51 900	16.4	43 100 (83.0%)	8800 (17.0%)	2 259 887 (58%)	–2.0	4354	–5.0
Y2014	318 892	46 179	14.5	53 500	16.8	44 600 (83.4%)	8900 (16.5%)	2 255 668 (57%)	–0.2	4216	–3.2
Per cent change from 2000 to 2014	13.0	31.7	16.8	35.0	19.8	30.2	65.7	168.7	–	99.0	
Geometric average change %)	0.9	2.0		2.2		1.9	3.7	7.3	–	5.0	

*Epidural services=62310—cervical/thoracic interlaminar epidural injections; 62311—lumbar/sacral interlaminar epidural injections; 64479—cervical/thoracic transforaminal epidural injections; 64480—cervical/thoracic transforaminal epidural injections add-on; 64483—lumbar/sacral transforaminal epidural injections; 64484—lumbar/sacral transforaminal epidural injections add-on.

Table 2 Utilisations of epidural injections in the fee-for-service Medicare population from 2000 to 2014

	Cervical/thoracic interlaminar epidurals (CPT 62310)			Lumbar interlaminar and caudal epidurals (CPT 62311)			Cervical/thoracic transforaminal epidurals					Lumbar/sacral transforaminal epidurals				
	Services	Rate	Per cent of change from previous year	Services	Rate	Per cent of change from previous year	CPT 64479 Services	CPT 64480 Services	Total Services	Rate	Per cent of change from previous year	CPT 64483 Services	CPT 64484 Services	Total Services	Rate	Per cent of change from previous year
2000	75 741	191	—	618 362	1560	—	13 454	9434	22 888	58	—	85 006	37 477	122 483	309	—
2001	84 385	211	10.3	702 713	1755	12.5	14 732	8537	23 269	58	0.6	125 534	53 133	178 667	446	44.4
2002	99 117	245	16.1	786 919	1943	10.7	18 583	10 835	29 418	73	25.0	177 679	79 115	256 794	634	42.1
2003	109 783	267	9.1	838 858	2040	5.0	21 882	15 769	37 651	92	26.0	242 491	114 046	356 537	867	36.7
2004	130 649	313	17.3	878 174	2104	3.2	25 182	18 094	43 276	104	13.3	363 744	196 044	559 788	1341	54.7
2005	141 652	333	6.5	945 350	2225	5.7	27 844	20 525	48 369	114	9.8	395 508	216 892	612 400	1441	7.4
2006	146 748	339	1.6	946 961	2185	−1.8	29 822	23 073	52 895	122	7.2	452 125	245 453	697 578	1610	11.7
2007	156 415	353	4.4	926 029	2092	−4.3	29 938	22 266	52 204	118	−3.4	506 274	274 305	780 579	1764	9.6
2008	165 636	365	3.2	905 419	1994	−4.7	32 286	24 003	56 289	124	5.1	572 340	317 448	889 788	1959	11.1
2009	175 503	383	5.1	888 166	1939	−2.7	37 012	27 487	64 499	141	13.6	632 658	351 685	984 343	2149	9.7
2010	184 750	394	2.8	888 421	1894	−2.3	40 003	29 888	69 891	149	5.8	679 117	383 128	1 062 245	2264	5.4
2011	200 134	414	5.2	914 324	1893	0.0	38 970	26 628	65 598	136	−8.8	710 638	398 519	1 109 157	2296	1.4
2012	213 390	424	2.4	925 179	1839	−2.8	35 945	21 293	57 238	114	−16.2	718 437	390 749	1 109 186	2205	−4.0
2013	217 393	419	−1.3	901 468	1737	−5.6	34 699	20 409	55 108	106	−6.7	700 820	385 098	1 085 918	2092	−5.1
2014	208 741	390	−6.9	815 858	1525	−12.2	37 944	21 587	59 531	111	4.8	763 793	407 745	1 171 538	2190	4.7
Per cent of change from 2000 to 2014																
Change	176	104	—	32	−2	—	182	129	160	93	—	799	988	856	609	—
Geometric average annual change (%)																
Geometric average	7.5	5.2	—	2.0	−0.2	—	7.7	6.1	7.1	4.8	—	17.0	18.6	17.5	15.0	—

Rate—per 100 000 Medicare beneficiaries.

Figure 1 Frequency of usage of epidural injections by procedures from 2000 to 2014, in Medicare recipients.

Figure 2 Frequency of usage of epidural injections and all other interventional pain management procedures from 2000 to 2014, in Medicare recipients.

However, the ratio of lumbosacral transforaminal epidural injections increased from 14.6% of all epidural injection in 2000 to 51.9% in 2014, thus, exceeding interlaminar epidural injections.

- Site-of-service usage patterns showed a decrease in HOPDs associated with a dramatic increase in in-office procedures.

DISCUSSION

Usage of epidural injections for chronic spinal pain in the FFS Medicare population in the USA increased

dramatically from 2000 to 2014. The increase for epidural injections has been shown to be 99% per 100 000 Medicare beneficiaries with an annual increase of 5%, compared to the increase of Medicare beneficiaries per 100 000 population of 35% with an annual increase of 2.2% during the same period. The increases were predominantly noted for lumbar transforaminal epidural injections with a 609% increase per 100 000 Medicare population from 2000 to 2014 with an annual increase of 15.0%. The increases were modest with 93% for cervical and thoracic transforaminal epidural injections and 104% for cervical and thoracic interlaminar epidural

injections per 100 000 Medicare population. Usage of cervical/thoracic interlaminar epidural injections decreased by 6.9%, from 217 393 to 208 741, from 2013 to 2014 and for lumbar/sacral interlaminar epidural injections 9% from 901 468 to 815 858, whereas there was an 8% increase in cervical/thoracic transforaminal epidural injections from 55 108 to 59 531 and an 8% increase in lumbar/sacral transforaminal epidural injections from 1 085 918 to 1 171 538. Dramatic increases were noted for lumbosacral transforaminal epidural injections from a baseline rate of 309 in 2000 to 2190 in 2014 for per 100 000 Medicare population, an increase of 609% or an annual rate of 15%. In contrast, interlaminar epidural injections in the lumbar spine, which also include caudal epidural injections, have decreased 2% with an annual decrease of 0.2% from 1560 in 2000 per 100 000 Medicare population to 1525 in 2014. Consequently, only interlaminar epidural injections correlated with overall Medicare beneficiary growth, which has been shown to be 35% and growth of Medicare beneficiaries above age 65 years vs below 65 years with 30.2% vs 65.7%. There was also change in site of service usage patterns with a decrease in HOPD use and a dramatic increase in in-office services. ASC share increased from 19.9% in 2002 to 27.7% in 2014 and in-office services dramatically increased from 25.8% in 2002 to 42.9% in 2014 (see online supplementary appendices 3 and 4), whereas HOPD share decreased from 54.3% to 29.4%.

As shown in online supplementary appendices 2 and 3, specialty characteristics showed that an overwhelming majority of the procedures (89.5%) were performed by pain management specialists, which essentially remained stable over the years. Surgery was a distant second specialty with 4.5% and radiology followed with 3.8% usage. Surgical specialties performed fewer procedures when compared to 2000, whereas radiologists performed more procedures. General physicians and other providers including Certified Registered Nurse Anesthetists, nurse practitioners and Physician Assistants also provided a lesser number of epidural injections than in 2000.

The results demonstrated in this evaluation were similar to other recently performed evaluations.^{11–15} However, these results are noteworthy compared to some of the previous studies, which focused on different aspects rather than assessment of growth and usage.^{47–49} Friedly *et al*^{47 48} and Abbott *et al*⁴⁹ indicate that injection therapies were provided with lack of evidence for managing chronic low back pain. Abbott *et al*⁴⁹ also included analysis of a publication from the Office of Inspector General in 2010⁵⁰ with multiple recommendations to curb the growth of lumbosacral transforaminal epidurals that showed a lack of significant effect or, at most, mild influence. Another paradoxical development is that transforaminal epidural injections have exceeded the total number of lumbar interlaminar and caudal epidural injections starting in 2009, which essentially reversed a long-standing trend of a high proportion of

interlaminar and caudal epidural injections compared to transforaminal epidural injections, despite multiple reports of complications and resultant warnings.^{1–5 11–15}

Some of the limitations for our assessment include lack of inclusion of patients participating in Medicare Advantage Plans, which could lead to exclusion of ~20–30% of the population. Further, there is also potential for coding errors and elimination of procedures which are not commonly used for spinal pain, such as continuous epidural injections and neurolytic procedures, may underestimate the number of procedures performed. However, the advantages of this study include that we have used the full Medicare data instead of an extrapolation and also all Medicare FFS population instead of using only those 65 years or older.

The increasing prevalence, disability, healthcare costs and human toll of spinal pain, the increasing usage of all modalities, specifically epidural injections—the subject of this assessment—continue to incite controversy and provide the basis of the claims that epidural injections are overused, leading to inappropriate use, abuse and fraud without evidence of efficacy, medical necessity and indications.^{12 24–26 37 38} The supporters of various modalities continue to profess cautious use with demonstration of effectiveness and cost utility, claim that spinal pain continues to increase, along with its understanding, which continues to evolve over the years.^{24–36 39 40 51} Thus, epidural injections in managing chronic spinal pain are justified with moderate evidence available in support of these injections in appropriately conducted randomised trials and systematic reviews.^{12 24–26 37 38 51} However, others have provided contradictory evidence with lack of effectiveness demonstrated in high-profile assessments.^{25 26 37} These reports have been extensively critiqued.^{24 27–32 52–56} In addition to substantial differences between proponents and opponents with the majority of the government-sponsored studies in the USA showing lack of effectiveness of epidural injections in managing low back and lower extremity pain, Lewis *et al*^{39 40} in two separate manuscripts funded by the National Health Services (NHS) and health technology assessment programme have presented positive results for epidural injections. In a systematic review and economic model of the clinical and cost-effectiveness of management strategies for sciatica performed for the health technology assessment,³⁹ results were positive for demonstrating the effectiveness of epidural corticosteroid injections. They⁴⁰ also showed, in a systematic review and network meta-analysis of comparative clinical effectiveness of management strategies for sciatica with review of 122 relevant studies and 21 treatment strategies, statistically significant improvement with epidural injections. In addition, network meta-analysis⁴⁰ also showed superiority of epidural injections to traction, percutaneous discectomy and exercise therapy.

Overall, this assessment shows a continued increase of usage from 2000 to 2011, with subsequent decreasing patterns of usage of epidural injections. However,

large-scale and seemingly inappropriate increases in usage are related to lumbar transforaminal epidural injections, whereas there was a net decrease of lumbar interlaminar and caudal epidural injections. Even though epidural injections have constituted smaller increases when compared to other modalities, with continued controversy and the increase of 609% in lumbosacral transforaminal epidural injections from 2000 to 2014, and associated major complications related to transforaminal epidural injections, caution must be exercised in performing these procedures, specifically transforaminal epidural injections. Thus, it is essential not only to develop appropriate evidence, but also to synthesise the evidence using up-to-date randomised controlled trials and proper methodology without confluence of bias. With such analysis of the data, there is no superiority for transforaminal epidural injections compared to interlaminar epidural injections in the lumbar or cervical spine.^{24 27 29 30 32 57 58}

CONCLUSIONS

The use of epidural injections escalated from 2000 to 2011 with a small decline since then. However, dramatic increases were shown in usage patterns of lumbar transforaminal epidural injections despite rare complications, warnings and measures reducing the overall impact.

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REFERENCES

- Rathmell JP, Benzon HT, Dreyfuss P, *et al.* Safeguards to prevent neurologic complications after epidural steroid injections: consensus opinions from a multidisciplinary working group and national organizations. *Anesthesiology* 2015;122:974–84.
- US Food and Drug Administration. Drug Safety Communications. FDA Drug Safety Communication: FDA requires label changes to warn of rare but serious neurologic problems after epidural corticosteroid injections for pain. <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM394286.pdf> (accessed 22 Mar 2016).
- Food and Drug Administration. Anesthetic and Analgesic Drug Products Advisory Committee Meeting. November 24–25, 2014. Epidural steroid injections (ESI) and the risk of serious neurologic adverse reactions. <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM422692.pdf> (accessed 22 Mar 2016).
- Manchikanti L, Candido KD, Singh V, *et al.* Epidural steroid warning controversy still dogging FDA. *Pain Physician* 2014;17:E451–74.
- Manchikanti L, Falco FJE, Benyamin RM, *et al.* Epidural steroid injections safety recommendations by the Multi-Society Pain Workgroup (MPW): more regulations without evidence or clarification. *Pain Physician* 2014;17:E575–88.
- Manchikanti L, Hirsch JA. Neurological complications associated with epidural steroid injections. *Curr Pain Headache Rep* 2015;19:482.
- Manchikanti L, Falco FJE. Safeguards to prevent neurologic complications after epidural steroid injections: analysis of evidence and lack of applicability of controversial policies. *Pain Physician* 2015;18:E129–38.
- Bogduk N, Brazenor G, Christophidis N, *et al.* Epidural use of steroids in the management of back pain. Report of working party on epidural use of steroids in the management of back pain. Canberra, Commonwealth of Australia: National Health and Medical Research Council, 1994:1–76.
- Rajasee SS, Bae HW, Kanim LE, *et al.* Spinal fusion in the United States: analysis of trends from 1998 to 2008. *Spine* 2012;37:67–76.
- Dart RC, Surratt HL, Cicero TJ, *et al.* Trends in opioid analgesic abuse and mortality in the United States. *N Engl J Med* 2015;372:241–8.
- Manchikanti L, Pampati V, Falco FJE, *et al.* Assessment of the growth of epidural injections in the Medicare population from 2000 to 2011. *Pain Physician* 2013;16:E349–64.
- Manchikanti L, Helm II S, Singh V, *et al.* Accountable interventional pain management: a collaboration among practitioners, patients, payers, and government. *Pain Physician* 2013;16:E635–70.
- Manchikanti L, Pampati V, Falco FJE, *et al.* Growth of spinal interventional pain management techniques: analysis of utilization trends and Medicare expenditures 2000 to 2008. *Spine* 2013;38:157–68.
- Manchikanti L, Pampati V, Falco FJE, *et al.* An updated assessment of utilization of interventional pain management techniques in Medicare population: 2000–2013. *Pain Physician* 2015;18:E115–27.
- Manchikanti L, Pampati V, Hirsch JA. Utilization of interventional techniques in managing chronic pain in Medicare population from 2000 to 2014: an analysis of patterns of utilization. *Pain Physician* 2016;19:E531–46.
- Atluri S, Sudarshan G, Manchikanti L. Assessment of the trends in medical use and misuse of opioid analgesics from 2004 to 2011. *Pain Physician* 2014;17:E119–28.
- Gaskin DJ, Richard P. The economic costs of pain in the United States. *J Pain* 2012;13:715–24.
- Martin BI, Turner JA, Mirza SK, *et al.* Trends in health care expenditures, utilization, and health status among US adults with spine problems, 1997–2006. *Spine* 2009;34:2077–84.
- Murray CJ, Atkinson C, Bhalla K, *et al.* US Burden of Disease Collaborators. The state of US health, 1999–2010: burden of diseases, injuries, and risk factors. *JAMA* 2013;310:591–608.
- Hoy D, March L, Brooks P, *et al.* The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. *Ann Rheum Dis* 2014;73:968–74.
- Hoy D, March L, Woolf A, *et al.* The global burden of neck pain: estimates from the global burden of disease 2010 study. *Ann Rheum Dis* 2014;73:1309–15.
- Freburger JK, Holmes GM, Agans RP, *et al.* The rising prevalence of chronic low back pain. *Arch Intern Med* 2009;169:251–8.
- Manchikanti L, Singh V, Falco FJE, *et al.* Epidemiology of low back pain in adults. *Neuromodulation* 2014;17(Suppl 2):3–10.
- Manchikanti L, Abdi S, Atluri S, *et al.* An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: Guidance and recommendations. *Pain Physician* 2013;16:S49–83.
- Chou R, Hashimoto R, Friedly J, *et al.* *Pain Management Injection Therapies for Low Back Pain*. Technology Assessment Report ESIB0813 (prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. HHSA 290–2012-00014-I). Rockville (MD): Agency for Healthcare Research and Quality; 20 March 2015.
- Pinto RZ, Maher CG, Ferreira ML, *et al.* Epidural corticosteroid injections in the management of sciatica: a systematic review and meta-analysis. *Ann Intern Med* 2012;157:865–77.
- Manchikanti L, Benyamin RM, Falco FJ, *et al.* Do epidural injections provide short- and long-term relief for lumbar disc herniation? A systematic review. *Clin Orthop Relat Res* 2015;473:1940–56.
- Manchikanti L, Nampiaparampil DE, Candido KD, *et al.* Do cervical epidural injections provide long-term relief in neck and upper extremity pain? A systematic review. *Pain Physician* 2015;18:39–60.
- Manchikanti L, Nampiaparampil DE, Manchikanti KN, *et al.* Comparison of the efficacy of saline, local anesthetics, and steroids in epidural and facet joint injections for the management of spinal pain: a systematic review of randomized controlled trials. *Surg Neurol Int* 2015;6:S194–235.

30. Manchikanti L, Kaye AD, Manchikanti KN, *et al.* Efficacy of epidural injections in the treatment of lumbar central spinal stenosis: a systematic review. *Anesth Pain Med* 2015;5:e23139.
31. Manchikanti L, Staats PS, Nampiaparampil DE, *et al.* What is the role of epidural injections in the treatment of lumbar discogenic pain: a systematic review of comparative analysis with fusion. *Korean J Pain* 2015;28:75–87.
32. Manchikanti L, Knezevic NN, Boswell MV, *et al.* Epidural injections for lumbar radiculopathy and spinal stenosis: a comparative systematic review and meta-analysis. *Pain Physician* 2016;19:E365–410.
33. Liu K, Liu P, Liu R, *et al.* Steroid for epidural injection in spinal stenosis: a systematic review and meta-analysis. *Drug Des Devel Ther* 2015;9:707–16.
34. Bicket MC, Gupta A, Brown CH, *et al.* Epidural injections for spinal pain: a systematic review and meta-analysis evaluating the “control” injections in randomized controlled trials. *Anesthesiology* 2013;119:907–31.
35. Lee J, Gupta S, Price C, *et al.*, British Pain Society. Low back and radicular pain: a pathway for care developed by the British Pain Society. *Br J Anaesth* 2013;111:112–20.
36. Macvicar J, King W, Landers MH, *et al.* The effectiveness of lumbar transforaminal injection of steroids: a comprehensive review with systematic analysis of the published data. *Pain Med* 2013;14:14–28.
37. Staal JB, de Bie RA, de Vet HC, *et al.* Injection therapy for subacute and chronic low back pain: an updated Cochrane review. *Spine* 2009;34:49–59.
38. Chou R, Hashimoto R, Friedly J, *et al.* Epidural corticosteroid injections for radiculopathy and spinal stenosis: a systematic review and meta-analysis. *Ann Intern Med* 2015;163:373–81.
39. Lewis RA, Williams N, Matar HE, *et al.* The clinical effectiveness and cost-effectiveness of management strategies for sciatica: systematic review and economic model. *Health Technol Assess* 2011;15:1–578.
40. Lewis RA, Williams NH, Sutton AJ, *et al.* Comparative clinical effectiveness of management strategies for sciatica: systematic review and network meta-analyses. *Spine J* 2015;15:1461–77.
41. Racoosin JA, Seymour SM, Cascio L, *et al.* Serious neurologic events after epidural glucocorticoid injection—the FDA’s risk assessment. *N Engl J Med* 2015;373:2299–301.
42. Kainer MA, Reagan DR, Nguyen DB, *et al.*, Tennessee Fungal Meningitis Investigation Team. Fungal infections associated with contaminated methylprednisolone in Tennessee. *N Engl J Med* 2012;367:2194–203.
43. Manchikanti L, Malla Y, Wargo BW, *et al.* A prospective evaluation of complications of 10,000 fluoroscopically directed epidural injections. *Pain Physician* 2012;15:131–40.
44. Atluri S, Glaser SE, Shah RV, *et al.* Needle position analysis in cases of paralysis from transforaminal epidurals: Consider alternative approaches to traditional technique. *Pain Physician* 2013;16:321–34.
45. Specialty utilization data files from Centers for Medicare and Medicaid Services. <http://www.cms.hhs.gov/> (accessed 22 Mar 2016).
46. Vandenbroucke JP, Von Elm E, Altman DG, *et al.*, Iniciativa STROBE. Strengthening the reporting of observational studies in epidemiology (STROBE): Explanation and elaboration. *Gac Sanit* 2009;23:158.
47. Friedly J, Chan L, Deyo R. Increases in lumbosacral injections in the Medicare population: 1994 to 2001. *Spine* 2007;32:1754–60.
48. Friedly J, Chan L, Deyo R. Geographic variation in epidural steroid injection use in Medicare patients. *J Bone Joint Surg Am* 2008;90:1730–7.
49. Abbott ZI, Nair KV, Allen RR, *et al.* Utilization characteristics of spinal interventions. *Spine J* 2012;12:35–43.
50. US Department of Health and Human Services. Office of Inspector General (OIG). Inappropriate Medicare Payments for Transforaminal Epidural Injection Services (OEI-05-09-00030). August 2010. <http://oig.hhs.gov/oei/reports/oei-05-09-00030.pdf> (accessed 22 Mar 2016).
51. Manchikanti L, Falco FJE, Pampati V, *et al.* Cost utility analysis of caudal epidural injections in the treatment of lumbar disc herniation, axial or discogenic low back pain, central spinal stenosis, and post lumbar surgery syndrome. *Pain Physician* 2013;16:E129–43.
52. Manchikanti L, Benyamin RM, Falco FJE, *et al.* Guidelines warfare over interventional techniques: is there a lack of discourse or straw man? *Pain Physician* 2012;15:E1–26.
53. Manchikanti L, Kaye AD, Hirsch JA. Comment RE: Chou R, Hashimoto R, Friedly J, *et al.* RE: Epidural corticosteroid injections for radiculopathy and spinal stenosis: a systematic review and meta-analysis. *Ann Intern Med* 2015;163:373–81. *Ann Intern Med* 2016;164:633.
54. Manchikanti L, Boswell MV. Appropriate design and methodologic quality assessment, clinically relevant outcomes are essential to determine the role of epidural corticosteroid injections. Commentary RE: Chou R, Hashimoto R, Friedly J, *et al.* Epidural corticosteroid injections for radiculopathy and spinal stenosis: a systematic review and meta-analysis. *Ann Intern Med* 2015;163:373–81. *Evid Based Med*; 17 February 2016.
55. Eden J, Levit L, Berg A, *et al.*, eds. Committee on Standards for Systematic Reviews of Comparative Effectiveness Research; Institute of Medicine. *Finding what works in health care. Standards for systematic reviews*. Washington (DC): The National Academies Press, 2011.
56. Cappola AR, FitzGerald GA. Confluence, not conflict of interest: name change necessary. *JAMA* 2015;314:1791–2.
57. Chang Chien GC, Knezevic NN, McCormick Z, *et al.* Transforaminal versus interlaminar approaches to epidural steroid injections: a systematic review of comparative studies for lumbosacral radicular pain. *Pain Physician* 2014;17:E509–24.
58. Manchikanti L, Singh V, Pampati V, *et al.* Comparison of the efficacy of caudal, interlaminar, and transforaminal epidural injections in managing lumbar disc herniation: Is one method superior to the other? *Korean J Pain* 2015;28:11–21.