

Health Policy Review

Percutaneous Adhesiolysis Procedures in the Medicare Population: Analysis of Utilization and Growth Patterns from 2000 to 2011

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Disclaimer information on P. E136.

Manuscript received: 01-28-2014
Accepted for publication:
02-10-2014

Free full manuscript:
www.painphysicianjournal.com

Background: Multiple reviews have shown that interventional techniques for chronic pain have increased dramatically over the years. Of these interventional techniques, both sacroiliac joint injections and facet joint interventions showed explosive growth, followed by epidural procedures. Percutaneous adhesiolysis procedures have not been assessed for their utilization patterns separately from epidural injections.

Study Design: An analysis of the utilization patterns of percutaneous adhesiolysis procedures in managing chronic low back pain in the Medicare population from 2000 to 2011.

Objective: To assess the utilization and growth patterns of percutaneous adhesiolysis in managing chronic low back pain.

Methods: The study was performed utilizing the Centers for Medicare and Medicaid Services (CMS) Physician Supplier Procedure Summary Master of Fee-For-Service (FFS) Data from 2000 to 2011.

Results: Percutaneous adhesiolysis procedures increased 47% with an annual growth rate of 3.6% in the FFS Medicare population from 2000 to 2011. These growth rates are significantly lower than the growth rates for sacroiliac joint injections (331%), facet joint interventions (308%), and epidural injections (130%), but substantially lower than lumbar transforaminal injections (665%) and lumbar facet joint neurolysis (544%).

Limitations: Study limitations include lack of inclusion of Medicare Advantage patients. In addition, the statewide data is based on claims which may include the contiguous or other states.

Conclusion: Percutaneous adhesiolysis utilization increased moderately in Medicare beneficiaries from 2000 to 2011. Overall, there was an increase of 47% in the utilization of adhesiolysis procedures per 100,000 Medicare beneficiaries, with an annual geometric average increase of 3.6%.

Key words: Interventional techniques, chronic spinal pain, epidural steroid injections, percutaneous adhesiolysis, post surgery syndrome, spinal stenosis

Pain Physician 2014; 17:E129-E139

Chronic low back and lower extremity pain is pervasive, disabling, and expensive (1-4). Martin et al (4) assessed health care expenditures in the United States in 2005 for treating back and neck problems, with the results illustrating a 49% increase in the number of patients seeking spine-related care

from 1997 to 2005 and with an increase in expenses of 65% to \$86 billion in 2005. Imaging, drug use, physical therapy, surgery, interventional techniques, and other treatments have increased at an explosive pace over the past decade, leading to numerous regulations (5-12). Consequently, interventional techniques

including percutaneous adhesiolysis are considered as one of the major components contributing to increasing expenditures among patients with chronic low back pain. Percutaneous adhesiolysis has been criticized even though multiple randomized trials and systematic reviews have demonstrated the efficacy and effectiveness of the intervention in chronic recalcitrant low back and lower extremity pain (10,13-24).

Persistent low back pain caused by intervertebral disc herniation, spinal stenosis, spondylolisthesis, and internal disc derangement is the most common reason for lumbar surgery (5,9,10,25). Persistent low back pain and disability following surgical intervention is relatively common (10,26-29). Overall, the literature estimates reoperation rates from 9.5% to 25%, leading to post lumbar surgery syndrome, complaints, and disability with escalating surgical interventions with complex fusions (5,8,9,26-31). This increase of surgical interventions has been described as out of sync with scientific evidence regarding the risks and benefits of surgical interventions, specifically with spinal fusion (5,28-31). Some of post surgery syndrome ailments may be treated with interventional techniques including percutaneous adhesiolysis (10,13-24,32,33).

Percutaneous adhesiolysis has also been shown to be effective in chronic low back pain secondary to lumbar spinal stenosis (10,13,14,19,24). Spinal stenosis is the most common cause of surgical interventions including complex fusions (5,9,25,27-31). Chronic low back pain with lower extremity pain secondary to spinal stenosis has been managed with multiple interventional techniques (10,32-35). Thus, prior to considering other invasive modalities such as spinal cord stimulation, intrathecal infusion systems, or further surgical intervention, percutaneous adhesiolysis may be considered in managing chronic low back and lower extremity pain (10,13-24). Recently, the escalating growth of spinal interventional techniques (per 100,000 Medicare beneficiaries) has been highlighted with a 331% increase of sacroiliac joint injections, 308% increase of facet joint interventions, and 130% increase of epidural injections (11,12). Furthermore, it has also been reported that there has been a 665% increase of lumbar transforaminal epidural injections (11) and 544% increase of lumbar facet joint neurolytic procedures (11). In addition, percutaneous adhesiolysis has been denied coverage by multiple insurers including a potential noncoverage policy decision by Noridian Healthcare Solutions (36-39).

This assessment has been undertaken to evaluate

the utilization patterns of percutaneous adhesiolysis utilizing a Racz catheter for various indications including post surgery syndrome and central spinal stenosis in the Medicare population from 2000 to 2011.

METHODS

The U.S. Centers for Medicare and Medicaid Services (CMS) Physician Supplier Procedure Summary Master Data from 2000 to 2011, purchased by the American Society of Interventional Pain Physicians (ASIPP), was utilized for this analysis (40). It is expected that the CMS's 100% data set is unbiased and unpredictable in terms of any individual patient characteristics. Medicare, with elderly and disabled fee-for-service (FFS), represents the single largest health care payer in the United States, with over 46.9 million beneficiaries in 2011. Thus, the procedures performed on FFS Medicare beneficiaries represent a large proportion of the adhesiolysis procedures in this analysis. Utilization rates were calculated based on Medicare beneficiaries for the corresponding year and are reported as procedures per 100,000 Medicare beneficiaries.

The Current Procedural Terminology (CPT) procedure codes (CPT 62263 and 62264) for percutaneous adhesiolysis were identified for the years 2000 to 2011. Furthermore, the data was analyzed based on the place of service – facility (ASC, HOPD) or non-facility (office).

Utilization patterns were identified for providers of various specialties. Providers were identified based on their specialty designation in the United States, including interventional pain management -09, pain medicine -72, anesthesiology -05, physical medicine and rehabilitation -25, neurology -13, psychiatry -26, for interventional pain management; orthopedic surgery -20, neurosurgery -14, and general surgery -02 as surgical specialties as a group; all other physicians and all other providers were identified as other providers.

The analysis of utilization data was performed using SPSS (9.0) statistical software, Microsoft Access 2003, and Microsoft Excel 2003. The procedure rates were calculated per 100,000 Medicare beneficiaries.

RESULTS

The results were assessed to show the overall characteristics of Medicare beneficiaries in the U.S. population as well as utilization of adhesiolysis procedures, utilization characteristics, and specialty characteristics showing each group of specialties and individual specialties.

Characteristic Features

From 2000 to 2011, the U.S. population increased 11%, with an annual increase of 1%, whereas the number of individuals 65 or over increased 17% with an annual increase of 1.5% (Table 1). However, Medicare beneficiaries overall increased 18% with an annual increase of 1.5% attributed to 14% of those over 65 years of age and 45% to those under 65 years. The annual increase seen among those less than 65 years was 3.4%, whereas it was 1.2% per year in those 65 or over. This is an important characteristic, as many patients with post lumbar surgery are nonresponsive to other modalities of treatments for disc herniation and other causes and are also younger than 65-year-old Medicare beneficiaries.

Table 2 shows utilization characteristics for percutaneous adhesiolysis procedures for a one-day procedure and a multi-day procedure, and a total service rate per 100,000 Medicare beneficiaries that increased 45% with

an annual increase of 3.6%. Of these, however, the utilization of multi-day procedures (CPT 62263) declined 91% from 2000 to 2011, whereas the utilization of one-day procedures (CPT 62264) increased 29% significantly from 2003 to 2011.

Specialty Characteristics

Utilization characteristics based on specialty are a crucial element in modern medicine for providing value-based interventional pain management (11,12,36). Table 3 and Fig. 1 illustrate significant variations among the specialties, their proportion of usage, and increases. Interventional pain management specialties including interventional pain management, pain medicine, neurology and psychiatry, and the 3 primary basic specialties of anesthesiology, physical medicine and rehabilitation, showed an increase of 58% per 100,000 Medicare beneficiaries with an overall increase of 47%.

Table 1. Characteristics of Medicare beneficiaries and adhesiolysis procedures.

Year	U.S. Population (,000)			Medicare Beneficiaries (,000)						Adhesiolysis Procedures		
	All Ages	≥ 65 years	Percent	< 65 years	Percent	≥ 65 years	Percent	Total Medicare beneficiaries	% to U.S.	Services	% of Change from Previous Year	Rate per 100,000 Medicare Beneficiaries
Y2000	282,172	35,077	12.4%	5,370	13.5%	34,262	86.5%	39,632	14.0%	8,778 (91%)		22
Y2001	285,040	35,332	12.4%	5,567	13.9%	34,478	86.1%	40,045	14.0%	10,966 (89%)	25%	27
Y2002	288,369	35,605	12.3%	5,805	14.3%	34,698	85.7%	40,503	14.0%	15,154 (83%)	38%	37
Y2003	290,211	35,952	12.4%	6,078	14.8%	35,050	85.2%	41,126	14.2%	16,916 (81%)	12%	41
Y2004	292,892	36,302	12.4%	6,402	15.3%	35,328	84.7%	41,729	14.2%	16,780 (77%)	-1%	40
Y2005	295,561	36,752	12.4%	6,723	15.8%	35,777	84.2%	42,496	14.4%	18,364 (77%)	9%	40
Y2006	299,395	37,264	12.4%	7,022	16.2%	36,317	83.8%	43,339	14.5%	17,903 (74%)	-3%	43
Y2007	301,290	37,942	12.6%	7,297	16.5%	36,966	83.5%	44,263	14.7%	17,334 (73%)	-3%	41
Y2008	304,056	38,870	12.8%	7,516	16.6%	37,896	83.4%	45,412	14.9%	16,768 (73%)	-3%	39
Y2009	307,006	39,570	12.9%	7,624	16.6%	38,177	83.3%	45,801	14.9%	16,493 (70%)	-2%	37
Y2010	308,746	40,268	13.0%	7,923	16.9%	38,991	83.1%	46,914	15.2%	15,550 (67%)	-6%	36
Y2011	313,848	41,122	13.1%	7,786	16.6%	39,132	83.4%	46,918	14.9%	15,322 (64%)	-1%	33
Change	11%	17%		45%		14%		18%		75%		47%
(GM)	1.0%	1.5%		3.4%		1.2%		1.5%		5.2%		3.6%

GM - Geometric average annual change

Table 2. Utilization of multi-day and one-day adhesiolysis procedures in the Medicare population from 2000 to 2011.

Year	62263 Multi-Day Adhesiolysis Procedures		62264 -One Day Adhesiolysis Procedures		Adhesiolysis Procedures	
	Services	Rate	Services	Rate	Total Services	Rate
2000	8,778	22			8,778	22
2001	10,463	26	503	1	10,966	27
2002	14,430	36	724	2	15,154	37
2003	7,183	17	9,733	24	16,916	41
2004	2,628	6	14,152	34	16,780	40
2005	2,972	7	15,392	36	18,364	43
2006	2,146	5	15,757	36	17,903	41
2007	1,553	4	15,781	36	17,334	39
2008	1,269	3	15,499	34	16,768	37
2009	1,199	3	15,294	33	16,493	36
2010	1,023	2	14,527	31	15,550	33
2011	948	2	14,374	31	15,322	33
Change from 2000	-89%	-91%	48%	29%*	75%	47%
GM	-18%	-20%	5.0%	3.3%*	5.2%	3.6%

GM - Geometric average annual change. * - From 2003 to 2011

Overall services have increased 75% with an annual geometric increase of 5.2%, whereas physical medicine and rehabilitation as a primary specialty showed an increase of 395% with an annual geometric change of 15.6%, despite many of them being categorized with specialty designations of interventional pain management and pain management or pain medicine. In reference to the number of procedures performed by various specialties, anesthesiologists excluding those designated with the specialty of interventional pain management and pain management constituted the highest proportion with 46% or 6,975 of the total of 15,322, despite many of the anesthesiologists being assigned as interventional pain management or pain management. In fact, there has been only less than a 1% decrease in the procedures performed by anesthesiologists from 7,521 in 2000 to 6,975 in 2011, at which time the specialty of pain management or interventional pain management did not exist. This illustrates the wide array of appeal of the procedure among 2 different specialties of anesthesiology and physical medicine and rehabilitation, even though they do not designate them as interventional pain management or pain management.

Discussion

Percutaneous adhesiolysis for the management of chronic low back and lower extremity pain has increased 47% with an annual increase of 3.6% from

2000 to 2011 among 100,000 FFS Medicare beneficiaries. These increases are significantly lower than the most commonly performed procedures as an overall group, including epidural injections, which showed an increase of 130%, a 308% increase for facet joint interventions, and a 331% increase in sacroiliac joint interventions (11,12). These increases are also dramatically lower than lumbar transforaminal epidural injections, which showed an increase of 665%, and lumbar facet joint neurolytic procedures, which showed an increase of 544% (12). Medicare beneficiaries per 100,000 population, on the other hand, increased by only 18% with an annual increase of 1.5%.

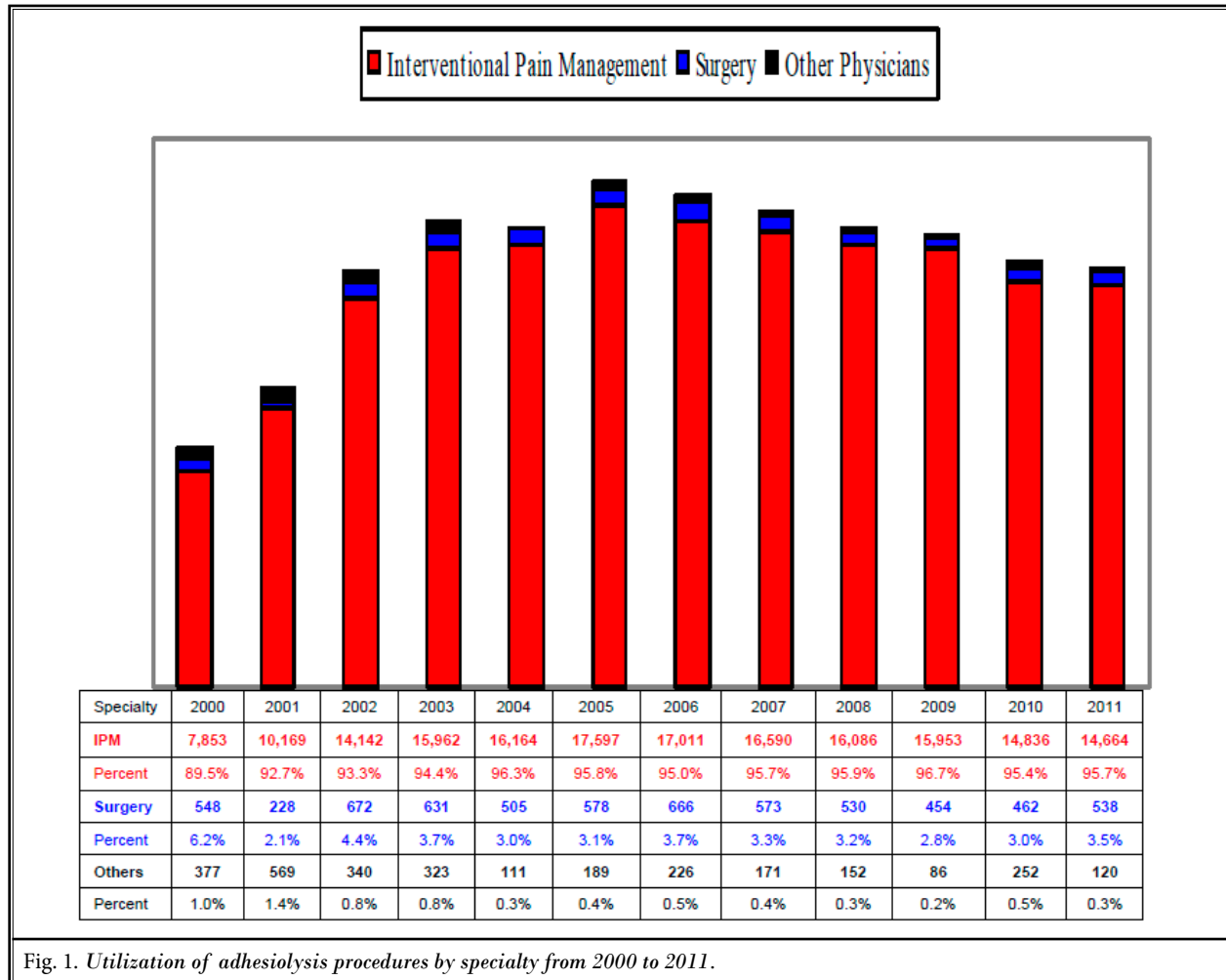
Since there were no previous assessments analyzing the growth and utilization patterns of percutaneous adhesiolysis, the results of the present assessment may not be compared with other studies. In addition, multiple other factors identified in the assessment of transforaminal epidural injections and facet joint injections have not been applied to the present assessment. Those factors were compiled by Office of Inspector General (OIG) publications, which showed substantial increases of both procedures and yet lacked appropriate documentation with concerns expressed by authorities leading to widespread concern among insurers and policy-makers (10-12,36,41,42). In fact, Noridian Healthcare Solutions has published a noncoverage decision for percutaneous adhesiolysis based on an inadequate assessment (39). While epidural injections,

Percutaneous Adhesiolysis Procedures in the Medicare Population

Table 3. Frequency of utilization of adhesiolysis procedures by specialty from 2000 to 2011 in Medicare recipients.

Specialty	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	% of Change from 2000	GM
Anesthesiology	7,521	9,922	11,845	12,069	9,090	9,893	9,117	8,326	7,975	7,865	7,083	6,975	-7%	-0.7%
Interventional Pain Management	0	0	0	725	2,866	3,067	3,388	4,262	5,110	4,940	5,160	4,852	-	-
Pain Management	0	26	1,702	2,442	3,044	3,385	3,262	2,733	1,703	1,673	1,429	1,527	-	-
Physical Medicine and Rehabilitation	247	168	538	652	1,103	1,185	1,216	1,220	1,256	1,390	1,122	1,222	395%	15.6%
Neurology	85	53	57	74	61	67	25	45	31	78	40	87	2%	0.2%
Psychiatry	0	0	0	0	0	0	3	4	11	7	2	1	-	-
Interventional Pain Management	7,853	10,169	14,142	15,962	16,164	17,597	17,011	16,590	16,086	15,953	14,836	14,664	87%	5.8%
Percent	89.5%	92.7%	93.3%	94.4%	96.3%	95.8%	95.0%	95.7%	95.9%	96.7%	95.4%	95.7%	7%	0.6%
Rate	19.8	25.4	34.9	38.8	38.7	41.4	39.3	37.5	35.4	34.8	31.6	31.3	58%	4.2%
Neurosurgery	193	42	35	63	42	51	83	89	49	36	16	31	-84%	-15.3%
Orthopedic Surgery	78	113	426	431	425	479	439	385	368	400	431	487	524%	18.1%
General Surgery	277	73	211	137	38	48	144	99	113	18	15	20	-93%	-21.3%
Surgery	548	228	672	631	505	578	666	573	530	454	462	538	-2%	-0.2%
Percent	6.2%	2.1%	4.4%	3.7%	3.0%	3.1%	3.7%	3.3%	3.2%	2.8%	3.0%	3.5%	-44%	-5.1%
Rate	1.4	0.6	1.7	1.5	1.2	1.4	1.5	1.3	1.2	1.0	1.0	1.1	-17%	-1.7%
Interventional Radiology	0	0	0	1	0	5	0	3	2	7	97	3	-	-
Diagnostic Radiology	0	0	0	7	0	15	5	0	22	8	4	1	-	-
Family Practice	20	0	0	11	0	7	18	3	7	8	11	11	-45%	-5.3%
General Practice	156	88	0	8	25	40	60	70	12	8	3	1	-99%	-36.8%
Internal Medicine	0	44	93	104	38	53	78	14	7	5	17	13	-	-
Emergency Medicine	99	99	118	166	27	35	29	32	40	33	45	37	-63%	-8.6%
Others specialties	102	338	129	26	21	34	36	49	62	17	75	54	-47%	-5.6%
Other Providers	377	569	340	323	111	189	226	171	152	86	252	120	-68%	-9.9%
Percent	1.0%	1.4%	0.8%	0.8%	0.3%	0.4%	0.5%	0.4%	0.3%	0.2%	0.5%	0.3%	-73%	-11.3%
Rate	1.0	1.4	0.8	0.8	0.3	0.4	0.5	0.4	0.3	0.2	0.5	0.3	-73%	-11.3%
Total Adhesiolysis Services	8,778	10,966	15,154	16,916	16,780	18,364	17,903	17,334	16,768	16,493	15,550	15,322	75%	5%
Rate	22	27	37	41	40	43	41	39	37	36	33	33	47%	3.6%

Rate per 100,000 Medicare Beneficiaries GM - Geometric average annual change



facet joint interventions, and sacroiliac joint interventions are being utilized at a high rate, leading to the claims that they are overused, inappropriately used, abused, and used without appropriate medical necessity and indications, the modest increases of percutaneous adhesiolysis should be considered as an individual procedure based on utilization and evidence, and be provided with appropriate coverage when indications and medical necessity are met (10-12,36). However, the Noridian decision was published without inclusion of extensive and seminal literature (13-15,17-21).

Even though some claim that there has not been an increase in disc herniation or radiculitis or chronic low back pain, the data shows conclusively that the increase in disability and the economic impact of chronic low back pain are a reality (1-5,10,43-53). The diagnosis of prevalence of low back pain has been estimated to increase substantially hand in hand with disability and

increasing costs (1-5,43-51). The increasing diagnosis of prevalence and appreciation of disability (1-3,50) may have significant developments in the understanding of the structural basis of chronic low back and lower extremity pain with the development of not only evidence-based medicine and comparative effectiveness research, but based on the principles of value-based and accountable interventional pain management (10-12,36). Consequently, when appropriate indications are met and are performed by well-trained physicians in proper settings after failure of other conservative modalities and fluoroscopically directed epidural injections, percutaneous adhesiolysis meets appropriate indications and medical necessity criteria and does not seem to present with abuse patterns (10,11,13-24).

In other cases with facet joint injections and transforaminal epidural injections, the OIG of Health and Human Services (HHS) has recommended strengthening

Medicare program standards as a means of safeguarding against improper payments for these procedures (11,36,41,42). Consequently, the CMS has established local coverage determinations (LCDs) across the country based on reasonable and necessary criteria. The establishment of LCDs, however, does not appear to have deterred the utilization patterns of epidural injections (especially transforaminal epidural injections), facet joint interventions (especially cervical and lumbar radiofrequency neurotomy procedures), and sacroiliac joint injections (11,12,36). To the contrary, transforaminal epidural injections and facet joint interventions have increased rather explosively at a rate of 665% and 544% per 100,000 Medicare population from 2000 to 2011 (11,12). For percutaneous adhesiolysis, there are very few LCDs except for the proposed LCD with non-coverage in Noridian states (39), and some Medicare Advantage plans issuing noncoverage based on the absence of LCDs (53). An appropriate preparation of an LCD for percutaneous adhesiolysis based on the program integrity manual (54) will meet reasonable and necessary provisions. Based on the program integrity manual (54), the LCD should consider reasonable and necessary provisions utilizing appropriate evidence to support any such LCD. The program integrity manual (54) clearly provides the following instructions for the LCDs. Thus, LCDs should be based on:

- ◆ Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- ◆ General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
 - Scientific data or research studies published in peer-reviewed medical journals
 - Consensus of expert medical opinion (i.e., recognized authorities in the field)
 - Medical opinion derived from consultations with medical associations or other health care experts.

Cost effectiveness has been illustrated not only for epidural injections, but for percutaneous adhesiolysis as well (55,56). Even though the Patient-Centered Outcomes Research Institute (PCORI) (57,58), by its founding legislation is not allowed to use cost effectiveness, it is indirectly considered by Medicare and (36), more importantly, by all private insurers. In fact, cost effectiveness or cost utility is the cornerstone of value-based

and accountable interventional pain management (11,36). Multiple cost effectiveness analysis studies and systematic reviews have been published over the years about managing spinal pain (55,59-63). However, there has been only one cost utility analysis utilizing data from controlled trials (14,15) of post surgery syndrome and central spinal stenosis in patients undergoing percutaneous adhesiolysis with a single day procedure (CPT 62264) (56). Thus, cost utility or effectiveness analysis of interventions with appropriate indications based on evidence-based medicine principles is essential (36,59). Cost utility analysis has been performed to estimate the ratio between the cost of a health-related intervention and the resulting benefit. Cost utility is estimated in terms of the number of years lived in full health by the patient receiving the intervention. Kepler et al (59), in a systematic review and cost utility analysis in spine care analyzing 33 studies with 60 cost utility ratios, showed that 27 of 60 or 45% of the cost utility assessments were less than \$100,000 per quality-adjusted life year (QALY) gained. The cost effectiveness of spinal cord stimulation has been demonstrated (60). A recent assessment of cost effectiveness analysis for surgery (61,62) showed that the cost per quality gained for surgery was \$69,403 or \$52,746 (76% of the total cost for cost utility) as a direct medical cost using general adult surgery cost and \$34,355 or \$23,017 (67% of the total cost) as a direct medical cost, using medical population surgery costs for disc herniation; whereas these costs were \$77,600 or \$48,112 as direct medical costs per QALY for spinal stenosis surgery with costs of \$115,600 or \$71,672 (62% of total cost) in direct medical costs for degenerative spondylolisthesis surgery.

The cost utility analysis of caudal epidural injections (55) utilizing data from 4 randomized trials (33,34,64,65) including 480 patients with robust outcome measures of 50% improvement in pain reduction and disability showed an average cost per one year per QALY of \$2,772.50 with 2 year follow-up. Cost utility analysis of percutaneous adhesiolysis (56) based on 2 well controlled trials (14,15) with long-term follow-up of 2 years in an experimental group of 130 patients receiving the treatment with post lumbar surgery syndrome and central spinal stenosis showed an average cost per one year QALY of \$2,650.

Thus, percutaneous adhesiolysis, as demonstrated in multiple randomized trials and reflected in systematic reviews and guidelines, has proven to be clinically effective based on high quality randomized trials (14,15,18) with favorable results with cost utility

analysis (56) that are similar to epidural injections and significantly less than surgery (61,62) and spinal cord stimulation (60,63). The cost utility analyses were performed in patients who are recalcitrant to various other modalities of treatments and are superior to surgical interventions (14,15).

There is also continued criticism of spine care providers with claims that decisions are neither informed nor consensual (66). A multitude of policy-makers also claim that informed consent in spine care often ignores key details in reference to the patient's diagnosis, risks and benefits of proposed treatments and procedures, the risks and benefits of alternative approaches, and the risks and benefits of not having the proposed procedures. However, with percutaneous adhesiolysis, these claims may not be appropriate as patients have long-standing pain, recalcitrant to multiple modalities of treatments, often surgical interventions, and are usually on high dose opioid medications (10,11,14-16,18,36,67,68).

There are several limitations to this assessment in that it only includes the FFS Medicare population, eliminating Medicare Advantage Plans. There is also a remote possibility of coding errors. The advantages of this study are that we have included all FFS Medicare patients, rather than only ones above the age of 65. Additional limitations include that the data was not available for all states individually and we were also unable to provide published facility and cost data for percutaneous adhesiolysis. Furthermore, one might claim that the state data may not be accurate as the claims processed in that state may be from contiguous or other states. Even then, this will not skew the data in any manner.

Overall, percutaneous adhesiolysis procedures have shown a modest increase and a much lower increase compared to multiple other interventional techniques.

Continued evidence development utilizing proper methodological criteria, development of LCDs with limitations or indications and medical necessity, and frequency may reduce further unforeseen increases or even modest increases (69).

CONCLUSION

The use of percutaneous adhesiolysis has increased modestly from 2000 to 2011. Emerging literature and multiple restrictions from the payer community requires appropriate consideration of these procedures. Thus, Medicare may develop LCDs with other insurers developing proper policies based on current literature.

ACKNOWLEDGMENTS

Contributors: Dr. Racz proposed the initial concept. Drs. Manchikanti and Helm developed the design for the study. Dr. Racz reviewed the design, concept, and approved.

Drs. Manchikanti and Helm prepared the initial draft. Mr. Pampati performed the statistical analysis. Dr. Racz reviewed, modified, and made corrections to the manuscript. The final manuscript was read, agreed, and approved by all authors.

Competing or Conflicts of Interest: None of the authors have any competing interest. Dr. Helm is a clinical investigator with Epimed and receives research support from Cephalon/Teva, AstraZeneca, and Purdue Pharma, LP. He has attended an advisory group meeting for Activas.

Dr. Racz is a consultant for and has family ownership of Epimed International, is a consultant to Cosman RF company, and has Medtronic patents.

Disclaimer: There was no external financial support. The support was from the first author's practice. The data was purchased by the American Society of Interventional Pain Physicians (ASIPP).

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