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Case Review

Declining Utilization of Percutaneous Epidural Adhesiolysis in Medicare Population: Evidence-Based or Over-Regulated?

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Background: Recent reviews have shown a reversal of growth of utilization of a majority of interventional techniques in the Medicare population post passage of the Affordable Care Act (ACA). Despite the presence of supportive evidence, there has been a significant decline in the utilization of percutaneous adhesiolysis. We hypothesize that this is most likely attributable to regulations governing interventional procedures and coverage policies.

Study Design: Assessment of utilization characteristics of percutaneous adhesiolysis procedures in managing chronic low back and lower extremity pain in fee-for-service (FFS) Medicare population.

Objective: To assess the utilization patterns of percutaneous adhesiolysis and correlation between regulations and declining utilization patterns.

Methods: FFS Medicare data from Centers for Medicare and Medicaid Services (CMS) Physician/Supplier Procedure Summary Master File from 2000 to 2016 was utilized.

Results: From 2009 to 2016, there was a decline of 53.2% with an annual decline of 10.3%, whereas from 2000 to 2009, overall increase was 62.6% with an annual increase of 6.5% per 100,000 Medicare population. The states controlled by Noridian Medicare carrier have shown a steep decline of 100% from 2009 to 2016 due to a noncoverage policy issued by Noridian.

Limitations: This analysis has not included Medicare Advantage Plans. However, an overwhelming majority of Medicare Advantage Plans do not cover adhesiolysis procedures.

Conclusion: Percutaneous adhesiolysis procedures faced a steep decline in utilization from 2009 to 2016 of 53.2% and an annual decline of 10.3% per 100,000 Medicare population. This is occurring simultaneous to an increase in the evidence base.

Key words: Interventional techniques, chronic low back pain, lower extremity pain, epidural injections, percutaneous adhesiolysis, post-surgery syndrome, spinal stenosis, neuroplasty

Percutaneous epidural adhesiolysis is a minimally invasive therapeutic modality used in the treatment of patients with chronic low back and lower extremity pain, nonresponsive to conservative modalities of management, as well as fluoroscopically directed epidural injections (1,2). The evolution of this technology dates back to the 1980s by Racz (3) with placement of a reinforced catheter, followed by percutaneous adhesiolysis and targeted placement of a catheter with injection of multiple anti-inflammatory solutions. Extensive literature of this technology has been published with randomized controlled trials (RCTs) (4-8), systematic reviews (1,2), and guidelines (9). Further, cost utility analysis of percutaneous adhesiolysis (10) was performed with favorable outcomes similar to epidural injections (11,12) with cost utility of $4,426 per one year of quality-adjusted life year (QALY) with one-day percutaneous adhesiolysis, with repeat procedures performed in post lumbar surgery syn-

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drome and spinal stenosis. Manchikanti et al (13), in an assessment of utilization characteristics, showed utilization of the adhesiolysis procedures to be 22 per 100,000 Medicare fee-for-service (FFS) population increasing to 33 by 2011, with a 47% total increase and an annual geometric increase of 3.6%.

A recent publication of utilization patterns of interventional techniques has shown a reversal of growth patterns following passage of the Affordable Care Act (ACA) (14). This analysis from 2000 to 2016 showed that epidural and adhesiolysis procedures had experienced significant declines in the utilization patterns overall of 11.6% and 1.7% per annum for 100,000 Medicare population from 2009 to 2016. This followed similar patterns of previous analysis (14-18).

Favorable evidence from RCTs and systematic reviews continues to accumulate for percutaneous adhesiolysis (1,2-9). Noridian has instituted a noncoverage policy leading to denial of the procedure by Medicare Advantage plans and multiple other insurers (19). In addition, the lack of local coverage determinations (LCDs) by many other carriers also has led Medicare Advantage plans to deny the service (20). Further, the overall health care milieu has changed with numerous regulations related to practice management affecting utilization of various procedures (21-35). Despite the changes, the United States' (US) spending on personal health care continues to rise with reduced access, without change in quality, despite opinions from proponents of these regulations (19-38).

Consequently, we hypothesized that the issue of noncoverage policy and negative publicity in the payor community continues to contribute to the decline in utilization of these percutaneous adhesiolysis procedures. This assessment is undertaken to describe utilization characteristics and assess the relationship between noncoverage policy and utilization in FFS Medicare population from 2000 to 2016.

METHODS

The utilization of percutaneous adhesiolysis was performed utilizing Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidance (39). Due to the nature of public data, approval by the Institutional Review Board (IRB) was not required. The data was nonattributable to individuals and is available through the Centers for Medicare and Medicaid Services (CMS) database (40).

STUDY DESIGN

The study was designed to assess utilization patterns of percutaneous adhesiolysis procedures in the FFS Medicare population in the US from 2000 to 2016.

Participants

Participants included the FFS Medicare recipients from 2000 to 2016.

For this analysis, the current procedure codes for percutaneous adhesiolysis (CPT 62264 and 62263) were utilized and allowed services were calculated. The data is calculated for overall services for each technique, and rate of services for 100,000 Medicare beneficiaries.

Data Compilation

The data was compiled using Microsoft Access 2010 and Microsoft Excel 2010 (Microsoft, Redmond, WA).

RESULTS

Utilization Characteristics

Table 1 shows the utilization patterns of percutaneous adhesiolysis procedures from 2009 to 2016 declined 53.2%, at an annual decline of 10.3% per 100,000 Medicare population. An overall decrease of 23.8% from 2000 to 2016 was with an annual decline of 1.7%. Further analysis showed that from 2000 to 2009, there was an increase in utilization patterns of 62.6% per 100,000 Medicare population with an annual increase of 6.5%. Table 1 also shows adhesiolysis procedures per 100,000 to peak in 2005 from 22 per 100,000 population in 2000 to 43 in 2005, and decline to 17 per 100,000 population with gradual decline over the years with a 95.5% decline from 2005 to 2016.

Figure 1 shows the frequency of utilization of 3-day and 1-day adhesiolysis procedures in Medicare population, with significant decline and disappearance of a 3-day procedure with an overall decline of all percutaneous adhesiolysis procedures.

Statewide Utilization Data

Table 2 shows the rate of utilization of percutaneous adhesiolysis procedures from 2009 to 2016 based on Medicare Administrative Contractors. Noridian, the largest carrier with a penchant for noncoverage policies, has shown the greatest decline (100%) for

Table 1. Utilization of 3-day and 1-day adhesiolysis procedures in the Medicare population from 2000 to 2016.

	62263 *3-day Adhesiolysis Procedures*			**62264*** *1-day Adhesiolysis Procedures*			**Adhesiolysis Procedures**		
Year	**Services**	**Rate**	**PCPY**	**Services**	**Rate**	**PCPY**	**Services**	**Rate**	**PCPY**
2,000	8,778	22	NA	-	-	NA	8,778	22	
2,001	10,463	26	18.0%	503	1	NA	10,966	27	23.6%
2,002	14,430	36	36.4%	724	2	NA	15,154	37	36.6%
2,003	7,183	17	-51.0%	9,733	24	NA	16,916	41	9.9%
2,004	2,628	6	-63.9%	14,152	34	43.3%	16,780	40	-2.2%
2,005	2,972	7	11.0%	15,392	36	6.8%	18,364	43	7.5%
2,006	2,146	5	-29.2%	15,757	36	0.4%	17,903	41	-4.4%
2,007	1,553	4	-29.1%	15,781	36	-1.9%	17,334	39	-5.2%
2,008	1,269	3	-20.4%	15,499	34	-4.3%	16,768	37	-5.7%
2,009	1,199	3	-6.3%	15,294	33	-2.2%	16,493	36	-2.5%
2,010	1,023	2	-16.7%	14,527	31	-7.3%	15,550	33	-8.0%
2,011	948	2	-10.0%	14,374	30	-3.9%	15,322	32	-4.3%
2,012	939	2	-4.9%	13,521	27	-9.7%	14,460	29	-9.4%
2,013	646	1	-33.3%	13,144	25	-5.8%	13,790	27	-7.6%
2,014	514	1	-22.8%	12,282	23	-9.4%	12,796	24	-10.0%
2,015	363	1	-31.2%	10,221	19	-18.9%	10,584	19	-19.4%
2,016	414	1	10.8%	9,116	16	-13.3%	9,530	17	-12.5%
Percentage of change from 2000 to 2016									
Change	-95.3%	-96.7%		-6.3%	-31.8%		8.6%	-23.8%	
GM	-17.4%	-19.2%		-0.5%	-2.9%		0.5%	-1.7%	
Percentage of change from 2000 to 2009									
Change	-86.3%	-88.2%		57.1%	41.1%		87.9%	62.6%	
GM	-17.5%	-18.5%		8.4%	7.1%		7.3%	6.5%	
Percentage of change from 2009 to 2016									
Change	-65.5%	-72.0%		-40.4%	-51.7%		-42.2%	-53.2%	
GM	-14.1%	-16.6%		-7.1%	-9.9%		-7.5%	-10.3%	

Rate- Per 100,000 population
GM- Geometric average annual change
PCPY- Percentage of change from previous year
* - for 62264 Change & GM are from 2003 to 2016 and from 2003 to 2009

all states from 2009 to 2016, versus an annual decline was 100% per 100,000 Medicare population. All the states except Missouri and Maryland have shown significant decreases.

DISCUSSION

The present assessment of utilization data of percutaneous adhesiolysis procedures in managing chronic low back and lower extremity pain in Medicare FFS population from 2000 to 2016 showed dramatic shifts with 53.2% or 10.3% annual rate of decline from 2009 to 2016 after enactment of ACA compared to 2000 to 2009 pre-ACA, which showed an increase of 62.6% or an annual increase of 6.5%. The dramatic changes have been attributed to the philosophical approach of ACA and other regulations (12,41,42), which increased the insurance, but at the same time reduced the coverage overall. This was also aided by multiple other factors such as LCDs with no coverage or no LCDs at all (19), reduced reimbursement (25,26), and an inappropriate analysis of evidence-base (12,41,42). The declines have been noted in spite of significant RCTs and systematic reviews publication (1,2,4-9). Further, cost utility analysis also showed

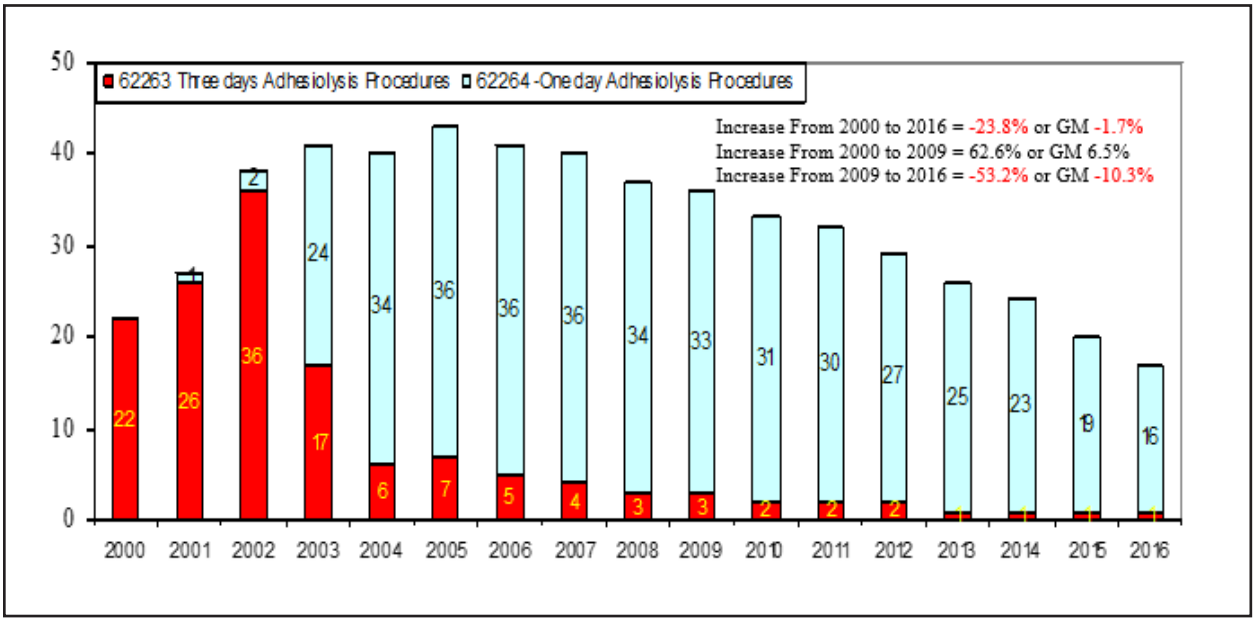

Fig 1. Frequency of utilization of 3-day and 1-day adhesiolysis procedures from 2000 to 2016, in Medicare recipients.

favorable outcomes at $4,426 for one- year of QALY compared to multiple other interventions, including spinal cord stimulation and surgical interventions, similar to epidural injections in patients with chronic recalcitrant pain after failure of various modalities of treatments and surgical intervention in the majority of cases (10,11,43-47).

The ACA, also known as Obamacare, along with many other regulations relating to the practice of medicine, was implemented with 3 primary goals; increasing the number of insured, improving the quality of care, and controlling health care costs (21-35). However, the regulations have increased practice management costs, shifted practices to the hospital-based, and significantly impacted independent practices; reducing access (18). US spending on personal health care and public health continues to rise with annual health care costs of $3.3 trillion for 2016 (36-38). In addition, Dieleman et al (37,38) in publications describing US spending on personal health care and public health, showed expenditures of $183.5 billion in managing musculoskeletal disorders, including low back and neck pain. Further, they argued that most of the increases were related to price increases, whereas CMS data showed that aging was one of the major factors. During the same time, pain and disability continued to escalate, along with opioid usage and opioid-related deaths (48,49). Even then, officials continue to make efforts to reduce utilization and reduce the reimbursement rates (25,26,35,50-55).

The claims of lack of increase in chronic spinal pain continue to be exaggerated (56-60). As Dieleman et al (37,38) have shown, overall spending on back and neck pain has substantially increased at a more rapid pace than many other conditions. Additionally, surgical interventions related to spinal pain with micro discectomies, open discectomies, decompression, and complex fusions continues to increase (61-63). Increasing disability secondary to low back pain has been described in conjunction with reports of increasing prevalence (50,58-60). Further, the increasing diagnosis of prevalence and appreciation of disability and increasing utilization of multiple different modalities, contributes to understanding the structural basis of chronic low back and lower extremity pain. This facilitates the development of technologies based on the principles of accountable and value-based interventional pain management (50,61-65). In actuality, the evidence for percutaneous adhesiolysis is better than many other modalities of treatments offered for low back and lower extremity pain, including surgical interventions in managing low back pain of post-surgery syndrome and spinal stenosis, with

Table 2. Rate of utilization of adhesiolysis procedures from 2009 to 2016, in FFS Medicare recipients by 2016 Medicare Administrative Contractors.

		Rate Per 100,000 Medicare Beneficiaries Population									
Carrier	**State**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**Change**	**GM**
Cahaba	Alabama	312.8	304.8	281.4	267.4	250.1	233.4	219.4	227.0	-27%	-4.5%
	Georgia	14.1	9.1	6.3	5.2	9.1	7.3	9.4	7.4	-48%	-8.8%
	Tennessee	4.1	5.9	5.2	4.4	2.2	2.4	1.7	1.6	-60%	-12.3%
	Total	91.7	87.6	79.5	74.8	70.5	65.0	61.7	62.6	-32%	-5.3%
CGS	Kentucky	68.9	68.2	69.8	55.3	43.0	30.7	29.9	24.0	-65%	-14.0%
	Ohio	37.6	26.6	29.7	18.9	16.3	11.7	12.8	9.6	-75%	-17.8%
	Total	46.5	38.5	41.2	29.4	24.0	17.2	17.7	13.7	-71%	-16.0%
First Coast	Florida	54.1	45.2	51.7	55.4	55.2	44.2	33.7	33.7	-38%	-6.5%
NGS	Connecticut	8.4	9.9	9.2	8.4	4.5	5.1	9.8	10.2	21%	2.7%
	Illinois	24.6	25.2	24.0	18.9	15.4	13.6	15.3	8.9	-64%	-13.6%
	Maine	16.6	9.8	8.5	6.9	6.7	10.3	4.0	4.2	-74%	-17.7%
	Massachusetts	13.5	8.7	11.6	9.8	10.2	12.4	18.2	17.7	31%	3.9%
	Minnesota	1.3	0.4	0.6	1.5	1.8	0.9	0.2	0.1	-92%	-29.8%
	New Hampshire	6.0	5.8	3.1	1.3	0.0	0.0	0.4	1.5	-75%	-17.9%
	New York	31.4	22.4	21.1	16.6	17.6	19.2	20.1	17.9	-43%	-7.7%
	Rhode Island	0.0	2.2	2.2	4.8	3.3	0.0	1.1	0.0		
	Vermont	7.4	9.0	2.6	1.7	0.0	0.0	0.0	0.0	-100%	-100.0%
	Wisconsin	9.1	7.2	5.6	3.8	7.8	9.4	6.3	6.4	-30%	-4.9%
	Total	19.5	15.7	15.0	12.0	11.7	12.3	13.3	11.3	-42%	-7.5%
Noridian	Alaska	0.0	1.5	0.0	4.3	0.0	10.8	0.0	21.0		
	Arizona	20.6	15.4	19.2	8.2	0.0	0.0	0.0	0.0	-100%	-100.0%
	California	50.1	61.4	62.9	62.9	60.9	43.4	11.1	0.0	-100%	-100.0%
	Idaho	3.6	0.9	2.5	0.0	0.0	0.0	0.0	0.0	-100%	-100.0%
	Montana	2.4	5.3	4.6	2.8	0.0	0.0	0.0	0.0	-100%	-100.0%
	Nevada	6.4	1.4	2.2	2.6	3.3	2.0	0.5	0.0	-100%	-100.0%
	North Dakota	0.0	0.0	0.0	0.9	0.0	0.0	0.0	0.0		
	Oregon	0.3	0.5	0.5	0.9	0.0	0.0	0.0	0.0	-100%	-100.0%
	South Dakota	9.7	7.3	1.4	5.0	0.0	0.0	0.0	0.0	-100%	-100.0%
	Utah	1.8	0.7	0.3	0.3	0.0	0.0	0.0	0.0	-100%	-100.0%
	Washington	6.4	3.4	3.5	3.4	0.1	0.0	0.0	0.0	-100%	-100.0%
	Wyoming	1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	-100%	-100.0%
	Total	31.0	35.9	37.1	35.9	32.7	22.7	6.0	1.1	-96%	-37.6%
Novitas	Arkansas	6.3	7.5	5.9	7.1	8.5	0.0	6.7	0.0	-100%	-100.0%
	Colorado	0.3	0.8	0.8	1.0	0.3	0.3	1.1	0.1	-62%	-12.8%
	DC	91.3	78.1	15.0	7.4	8.4	4.1	5.4	1.1	-99%	-46.6%
	Delaware	1.4	0.0	0.0	0.0	0.0	0.0	0.6	0.0	-100%	-100.0%
	Louisiana	21.9	19.1	11.5	23.4	13.1	10.0	10.9	16.0	-27%	-4.4%
	Maryland	4.6	3.7	2.2	3.5	2.7	2.2	2.3	6.6	43%	5.3%
	Mississippi	17.0	7.2	6.9	5.2	16.0	23.3	14.8	9.1	-46%	-8.5%
	New Jersey	38.8	43.0	19.8	9.6	11.8	10.4	11.4	13.1	-66%	-14.3%
	New Mexico	10.2	2.2	2.5	4.8	4.8	1.7	1.1	1.3	-87%	-25.2%

Table 2 (cont.). Rate of utilization of adhesiolysis procedures from 2009 to 2016, in FFS Medicare recipients by 2016 Medicare Administrative Contractors.

		Rate Per 100,000 Medicare Beneficiaries Population									
Carrier	State	2009	2010	2011	2012	2013	2014	2015	2016	Change	GM
	Oklahoma	25.7	21.7	24.1	23.3	20.3	20.8	36.8	38.3	49%	5.9%
	Pennsylvania	5.1	7.6	6.6	3.3	4.2	2.1	5.5	4.5	-12%	-1.8%
	Texas	108.6	89.9	88.2	80.7	71.6	77.9	66.2	52.1	-52%	-10.0%
	Total	40.7	35.7	31.4	28.3	26.2	27.1	25.5	21.5	-47%	-8.7%
Palmetto GBA	North Carolina	15.3	12.8	15.7	14.8	11.0	7.5	3.6	5.3	-66%	-14.1%
	South Carolina	9.8	7.9	7.6	9.9	6.8	10.7	8.3	6.7	-31%	-5.2%
	Virginia	8.6	12.0	11.1	7.5	5.0	7.7	7.5	8.4	-2%	-0.3%
	West Virginia	3.4	3.4	6.5	3.8	2.3	0.7	1.9	0.7	-79%	-20.0%
	Total	10.9	10.6	11.7	10.5	7.5	7.6	5.6	6.1	-44%	-8.0%
WPS	Indiana	13.9	9.1	8.4	5.1	5.7	4.4	5.1	1.8	-87%	-25.2%
	Iowa	0.6	0.8	1.0	0.2	2.4	0.7	0.7	0.3	-40%	-7.1%
	Kansas	45.8	26.8	13.2	27.9	33.7	20.5	18.4	17.7	-61%	-12.7%
	Michigan	68.5	66.0	53.0	47.2	42.7	42.4	39.2	31.5	-54%	-10.5%
	Missouri	6.7	5.1	5.6	7.3	15.3	30.5	27.1	33.5	401%	25.9%
	Nebraska	8.7	1.1	1.1	9.4	2.4	0.3	2.0	0.6	-93%	-31.2%
	Total	31.9	27.7	22.2	21.6	22.3	23.6	21.8	19.6	-39%	-6.7%

GM = Geometric average annual change

evidence also supporting the administration of the procedure in recalcitrant nonresponsive chronic disc herniation (2,8). Helm et al (2) in a systematic review of percutaneous adhesiolysis reviewed, 7 RCTs and 3 observational studies, meeting inclusion criteria. They provided strong or Level I evidence of the efficacy of percutaneous adhesiolysis in the treatment of chronic refractory low back and lower extremity pain. Other systematic reviews also provided similar evidence.

The LCDs for coverage of percutaneous adhesiolysis are very few with one noncoverage policy (Noridian) (13,64,65). Further, Medicare Advantage plans continue to issue noncoverage based on the absence of LCDs. Thus, it is crucial that an appropriate LCD is prepared for percutaneous adhesiolysis based on the Program Integrity Manual (66) meeting reasonable and necessary provisions. This manual along with revisions in the Cures Act clearly provide the instructions for utilization of published authoritative evidence derived from RCTs or other definitive studies. In addition, cost effectiveness has been illustrated for percutaneous adhesiolysis, along with multiple interventional techniques, in recent years utilizing the approach utilized for well-regarded cost utility analysis of surgical procedures (10,11,43-47). Based on this analysis, the cost utility of percutaneous adhesiolysis was calculated as direct costs and total costs extrapolated with 40% allocated for indirect costs. The cost of percutaneous adhesiolysis for one-year quality of improvement has been estimated as $4,426, higher than caudal epidural injection of $3,628, interlaminar epidural injections of $3,301, but similar to therapeutic medial branch blocks in managing chronic neck pain or low back pain of $4,261 or $3,715.85 (10,11,43-47). These reports favorably compared to overall cost effectiveness of disc herniation surgery of $69,403 per QALY, spinal stenosis, cost of $77,600 per QALY, and cost of $115,600 per QALY for degenerative spondylolisthesis (46,47).

Limitations of this assessment include that this review is restricted to only Medicare FFS population in the US with lack of inclusion of patients from Medicare Advantages plan. Bearing that in mind, given coverage decisions associated with Medicare Advantage, we believe that including this data would demonstrate even more significant reductions in or absence of utilization.

In summary, the noncoverage policy by Noridian influencing other insurers in declining to issue LCDs has resulted in diminution of percutaneous adheolysis

procedures. We believe that this has been detrimental to patient care. In addition, the reductions in payment by Medicare has also contributed to declining utilization.

CONCLUSION

From 2009 to 2016, percutaneous adhesiolysis procedures decreased substantially at a 53.8% overall per 100,000 population with an annual decrease of 10.3% due to ACA, multiple regulations, and inappropriate assessment of the literature leading to flawed conclusions and biases.

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