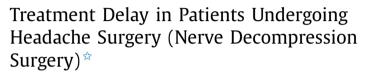
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ABSTRACT

Background: Although headache surgery has been shown to be an effective treatment option for refractory headache disorders, it has not been included as part of the headache disorder management algorithm by non-surgical providers. This study aims to evaluate the delay in surgical management of patients with headache disorders. In addition, a cost comparison analysis between conservative and operative treatment of headache disorders was performed, and the surgical outcomes of headache surgery were reported. *Methods:* Among 1112 patients who were screened, 271 (56%) pa-

tients underwent headache surgery. Data regarding the onset of headache disorder and pre- and postoperative pain characteristics were prospectively collected. To perform a cost comparison analysis, direct and indirect costs associated with the conservative treatment of headache disorders were calculated.

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Results: The median duration between onset of headache disorder symptoms and headache surgery was 20 (8.2-32) years. The annual mean cost of conservative treatment of headache disorders was \$49,463.78 (\$30,933.87-\$66,553.70) per patient. Over the 20-year time period before surgery, the mean cost was \$989,275.65 (\$618,677.31-\$1,331,073.99). In comparison, the mean cost of headache surgery was \$11,000. The median pain days per month decreased by 16 (0-25) (p<0.001), the median pain duration decreased by 14 (2-7) (p<0.001). *Conclusion:* This study shows that patients experience symptoms of headache disorders for an average of 20 years prior to undergoing headache pain but also reduces healthcare costs and should be implemented in the management algorithm of headache disorders.

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Introduction

Headache disorders (HD) are characterized by recurrent and persistent headache and include conditions such as migraine, tension-type headache, cluster headache, chronic daily headache, posttraumatic headache, trigeminal neuralgia, occipital neuralgia, and others.¹ The Global Burden of Disease study sheds light on the substantial impact of HD as a major global public-health concern affecting countries worldwide.^{2,3} The annual cost burden attributed solely to migraine has been estimated to surpass \$56 billion in the United States.⁴ Subsequently, a variety of pharmacologic treatments, nonpharmacologic treatments, and device-based interventions are available for patients with HD.^{5,6}

ders.

Patients with signs of nerve compression (localized pain pattern in the nerve distribution, tenderness upon palpation and dysesthesia resolved by local anesthetic injection), who have failed conservative treatment are candidates for headache surgery.^{7–10} Surgical intervention has been demonstrated to be a safe and low-risk outpatient procedure that results in significant improvement of symptoms in thousands of patients with HD.^{11–13}

However, headache surgery is not currently routinely considered as part of the management algorithm for HD by non-surgical providers. Consequently, patients often endure long periods of incomplete or suboptimal treatment with a significant impact on quality of life and potential avoidable healthcare costs.

This study aims to evaluate the delay of surgical treatment in patients with HD. In addition, a cost comparison analysis between conservative and operative treatment of HD is performed, and the surgical outcomes of headache surgery are reported.

Materials/Patients and Methods

Approval was obtained from the Internal Review Board at Massachusetts General Hospital and Weill Cornell Medical Center. Between September 2012 and November 2022, 1,112 consecutive patients presenting to the authors' (LG and WGA) headache surgery clinics with a neurologist-confirmed diagnosis of refractory HD were prospectively enrolled in this multi-center study. Patients with an unclear onset of HD symptoms and/or patients unable to provide informed consent were excluded. Screening criteria for headache surgery included: a) failure of conservative treatment b) symptoms and exam indicating nerve compression c) pain drawings following the anatomical nerve path d) positive response to nerve blocks.

All screening and surgical procedures were performed by authors LG and WGA. The surgeries were outpatient procedures carried out at an accredited surgery center. Data regarding demographics, onset of HD symptoms, work status, prior treatments and preoperative/postoperative pain characteristics were recorded using patient surveys at the first clinic visit and postoperatively at 3, 12, 24, 48, and 60 months. Data were stored in REDCap (version 8.1.20; Vanderbilt University, Nashville, TN.). Additionally, we performed a chart review to collect data on emergency department (ED) visits, imaging, and office visits for HD complaints.

As the primary endpoint, we assessed the surgical treatment delay (i.e., the duration between onset of HD symptoms and headache surgery) in HD patients. Secondary endpoints were a) a cost comparison analysis between conservative and operative treatment of HD and b) the outcomes of headache surgery. Postoperative outcomes were determined by calculating the relative and absolute increase/decrease in pain frequency (pain days per month), intensity (on a visual analogue scale of 0-10), and duration of pain (in hours).

Cost analysis

The cost analysis was based on healthcare utilization between the onset of HD symptoms and headache surgery. To calculate direct costs, oral drug regimes, conservative treatments, office visits to the neurology department and to other specialties due to HD symptoms, hospital admissions, imaging, and ED visits were included in the analysis. The unit cost and quantity of each variable were derived from previous research work.¹⁶⁻²⁶ The quantity of each variable was then multiplied by the utilization in our patient cohort and applied to the respective unit costs. The costs of oral drug therapy were deduced from the literature.⁴ The total direct cost of treatment was the sum of all variables. To calculate indirect costs associated with the conservative treatment of HD, data regarding long term (LT) disability, work absence (WA), the number of WA days per year and the number of days with reduced work productivity due to HD (presenteeism) was collected using patient surveys. It was assumed that patients with LT disability missed 260 days of work per year, which represents the total number of work days per calendar year. The yearly missed days of work were multiplied by the average hourly wage. To calculate the cost associated with presenteeism, the number of days with reduced work productivity was multiplied by the average hourly wage and by 0.5, as we estimated an average reduced productivity of 50%.¹⁴ We utilized the average hourly wage of \$33.46, a value obtained from the United States Bureau of Labor Statistics.¹⁵ It was assumed that employers generally cover the full wages for regular absences, while LT disability absences are usually compensated at 70% of the regular wage.¹⁵ Of note, all costs are reported in US dollars as of 2022 price data.

Data Analysis

Categorical data were shown as frequencies and percentages, continuous data as means and standard deviations, or as median and interquartile range in the case of heterogeneous variables. Continuous parameters were analyzed using the Wilcoxon signed-rank test. The statistical analysis was performed with RStudio (2020) (Integrated Development for R. RStudio, PBC, Boston, MA).¹⁶ A p-value of <0.05 was considered significant.

Results

The study population included 486 patients with refractory HD of which the majority were female (n=383, 79%). The mean patient age (at the time of screening) and age of HD symptom onset were 44 (\pm 14) and 23 (\pm 15) years, respectively. Demographic information is summarized in Table 1. Overall, 461 (97%) patients reported at least one concomitant HD including chronic migraine (n= 347, 75%), cluster headache (n= 38, 8.2%), trigeminal neuralgia (n= 14, 3.0%), cervicogenic headache (n= 8, 1.7%) and posttraumatic headache (n= 6, 1.3%). The majority of patients (n= 189, 55%) had a history of

| All patients (n = 486) n (%) |
|---------------------------------|
| 44 (14) |
| 383 (79) |
| |
| 386 (94) |
| 6 (1.5) |
| 4 (1.0) |
| 3 (0.7) |
| 10 (2.5) |
| |
| 353 (77) |
| 66 (14) |
| 29 (6.0) |
| 23 (15) |
| |

| Table 1 |
|---------------|
| Demographics. |

IQR, interquartile range; SD, standard deviation.

Missing values.

a = 79 missing.

 b = 29 missing.

head or neck injury. The median number of pain days was 30 days per month (24-30), the median pain duration was 24 hours (10-24), and the median pain intensity was 9.0 (8.0-10.0).

Preoperative treatment and workup

Preoperatively, all patients (n= 461, 100%) trialed a minimum of three different medication classes. Medication history included preventative HD medications (n= 342, 74%), abortive medications (n = 161, 35%), and opioid medications (n= 161, 35%). All patients (n= 461, 100%) received diagnostic nerve blocks, and 376 (77%) patients underwent botulinum toxin injections. Additional treatments ranged from acupuncture therapy (n= 136, 28%) to physical therapy (n= 98, 20%) and chiropractic therapy (n= 80, 16%) to radiofrequency ablation (n= 39, 8.0%) (Table 2). The majority of the patients (n= 298, 72%) underwent diagnostic imaging (i.e., MRI of the head and/or neck (n= 249, 60%), CT scan of the head and/or neck (n= 182, 44%), cervical X-ray (n= 31, 7.5%) and ultrasound of the affected nerve(s) (n= 18, 4.3%).

Surgical treatment delay

The median duration between the onset of HD symptoms and screening for headache surgery was 19 (7.4-32) years, while the median time to headache surgery was 20 (8.2-32) years.

Postoperative results

After screening, 271 (56%) patients underwent surgery. The majority of patients underwent occipital nerve decompression (i.e., greater occipital and/or lesser occipital nerve) decompression or neurectomy (n= 226, 83%), whereas frontal decompression (i.e., supraorbital and/or supratrochlear nerve) was performed in 75 (28%) patients, temporal decompression (i.e., auriculotemporal and/or zygomaticotemporal nerve decompression or avulsion) in 60 (22%) patients, and rhinogenic trigger point deactivation in nine (3.3%) patients. On average, the postoperative time of follow-up was 9.6 (\pm 7.0) months. The median pain days per month decreased by 16 days (0-25, 53% reduction) (p<0.001), the median pain intensity reduced by 4 points (2-7, 44% reduction) (p<0.001), and the median pain duration decreased by 11 hours (0-22, 46% reduction) (p<0.001). Total resolution of HD pain (i.e., 100% improvement of the pain) was observed in 65 (28%) patients. One hundred forty (61%) patients were found with at least 80% improvement of the pain, 41 (18%) patients reported at least 50% improvement of the pain, and 18 (7.9%) patients presented with at least 20% improvement. Pain improvement of 20% or less was found in 30 (13%) patients (Table 3).

Table 2

| | All patients $(n = 486)$ |
|---|--------------------------|
| Variable | n (%) |
| Number of different specialties visited, mean (SD) ^a Number of different treatments received, n (%) | 2.4 (1.7) |
| 2 | 80 (16) |
| 3 | 207 (42) |
| 4 | 88 (18) |
| >4 | 109 (22) |
| Type of treatment received, n (%) | |
| Oral medication | 486 (100) |
| Nerve blocks injection | 486 (100) |
| Injection with botulinum toxin | 376 (77) |
| Acupuncture | 136 (28) |
| Physical therapy | 98 (20) |
| Chiropractic therapy | 80 (16) |
| Radiofrequency ablation | 39 (8.0) |
| Neuro/biofeedback | 26 (5.3) |
| Nerve stimulation | 23 (4.7) |
| Medication use, n (%) ^b | |
| Anti-inflammatory medication | 264 (57) |
| Preventative medication | 342 (74) |
| Abortive medication | 307 (66) |
| Opioid medication | 161 (35) |
| Nerve medication | 178 (38) |
| Antiemetic medication | 264 (57) |

a = 67 missing.

b = 23 missing.

Table 3

Postoperative outcomes.

| Variable | All patients $(n = 271)$ | p value | |
|--|--------------------------|---------|--|
| Pain characteristics, median (IQR) ^a | | | |
| Decrease of pain frequency, days per month | 16 (0-25) | <0.001* | |
| Decrease of pain duration, hours | 11 (0-22) | <0.001* | |
| Decrease of pain intensity, 0-10 | 4 (2-7) | <0.001* | |
| Percent improvement in headache pain, n (%) ^b | | | |
| ≥80% | 140 (61) | | |
| ≥50% | 41 (18) | | |
| ≥20% | 18 (7.9) | | |
| | 30 (13) | | |

IQR, interquartile range.

* using Wilcoxon signed-rank test.

Missing values.

^a = 35 missing.

 $^{\rm b}$ = 42 missing.

Cost analysis

The mean annual direct cost of conservative treatment of HD amounted to \$14,076.48 (\$4,918.57-\$23,234.40) per patient. Nerve block injections accounted for 38% (\$5,376.80) of these costs, botulinum toxin injections for 32% (\$4,572.10) of the costs, and oral medication for 19% (\$2,713.00) of total direct costs (Table 4). The mean annual indirect cost was \$35,387.30 (\$26,015.30-\$43,319.30) with presenteeism accounting for 59% (\$20,879.04 (\$16,199.04-\$25,559.04)) of the costs, WA accounting for 27% (\$9,636.48 (\$6,036.48-\$11,796.48)) of the costs and LT disability accounting for 14% (\$4,871.78

M.H.J. Hazewinkel, K. Remy, L. Knoedler et al.

| Table 4 | 4 |
|---------|---|
|---------|---|

Annual direct cost.

| Variable | Unit costs | Quantity (per 20 years)* | Utilization (per 20 years) | Total average | | Ran | ige |
|---|---------------|-----------------------------|-------------------------------|-----------------------------|---------------------------|-----|-----------------------------|
| Oral medication | \$2713 | 20 | 100% | \$54,260.00 | | - | |
| Injection with botulinum | \$610- | 35 | 77% | \$91,441.35 | 16439.50 | - | 166443.20 |
| toxin | \$6,176.00 | | | | | | |
| Nerve blocks injection | \$252-\$4324 | 47 | 100% | \$107,536.00 | 11844.00 | - | 203228.00 |
| Acupuncture | \$50-\$150 | 6 | 28% | \$168.00 | 84.00 | - | 252.00 |
| Physical therapy | \$30-\$400 | 11.25 | 20% | \$483.75 | 67.50 | - | 900.00 |
| Chiropractic therapy | \$50-\$250 | 8 | 16% | \$192.00 | 64.00 | - | 320.00 |
| Radiofrequency ablation | \$2618-\$5267 | 7.5 | 8% | \$2,365.50 | 1570.80 | - | 3160.20 |
| Neuro/biofeedback | \$125-\$160 | 35 | 5.3% | \$264.34 | 231.88 | - | 296.80 |
| Transcutaneous electrical nerve stimulation | \$20-\$100 | 10 | 4.7% | \$28.20 | 9.40 | - | 47.00 |
| Office visit new patient neurology | \$170-\$220 | 1 | 100% | \$195.00 | 170.00 | - | 220.00 |
| Office visit established patient neurology | \$122-\$157 | 79 | 100% | \$11,020.50 | 9638.00 | - | 12403.00 |
| Office visit new patient | \$251-\$510 | 2.4 | 100% | \$913.20 | 602.40 | - | 1224.00 |
| Office visit for established patient | \$159-\$419 | 4.8 | 100% | \$1,387.20 | 763.20 | - | 2011.20 |
| Inpatient hospitalization following ED visit | \$7135-\$7499 | 2 | 7.8% | \$1,141.45 | 1113.06 | - | 1169.84 |
| MRI head/neck | \$500-\$11800 | 2 | 60% | \$7.380.00 | 600.00 | - | 14160.00 |
| CT head/neck | \$1000-\$9300 | 1 | 44% | \$2,266.00 | 440.00 | - | 4092.00 |
| Ultrasound | \$140-\$350 | 1 | 4.3% | \$10.54 | 6.02 | - | 15.05 |
| Cervical X-ray | \$90-\$220 | 1 | 7.5% | \$11.63 | 6.75 | - | 16.50 |
| Emergency department visit | \$768-\$782 | 3 | 20% | \$465.00 | 460.80 | - | 469.20 |
| Total Total per year | | | | \$281,529.65 \$14,076.48 | \$98,371.31 \$4,918.57 | | \$464,687.99 \$23,234.40 |

* Utilization was either calculated or was approximated based on literature.

Table 5

Annual indirect cost.

| Variable | Days (average, SD) | n (%) | Hourly wage Total cost (average, SD) | | Range | | nge |
|--|-----------------------|-------|--------------------------------------|-----------------------------|-----------------------------|---|------------------------------|
| Long term disability, not able to work | 260 | 10% | \$33.46 (7.5) | \$4,871.78 | \$3,779.78 | - | \$5,963.78 |
| Work absence | 60 (7.2) | 60% | \$33.46 (7.5) | \$9,636.48 | \$6,036.48 | - | \$11,796.48 |
| Presenteeism | 156 (7.1) | - | \$33.46 (7.5) | \$20,879.04 | \$16,199.04 | - | \$25,559.04 |
| Total Total per year | | | | \$707,746.00 \$35,387.30 | \$520,306.00 \$26,015.30 | | \$ 866,386.00 \$43,319.30 |

*We assumed that employers typically pay 100% of wages for work absence and 70% for long term disability.

(\$3,779.78-\$5,963.78)) of the total indirect costs (Table 5). Overall, the annual direct and indirect cost combined, resulted in \$49,463.78 (\$30,933.87-\$66,553.70) per patient. Over the 20-year period prior to surgery, the mean cost of conservative treatment of HD was \$989,275.65 (\$618,677.31-\$1,331,073.99). Headache surgery (average annual therapy costs of \$11,000) is equivalent to 2.6 months of conservative treatment.¹⁷⁻¹⁹

Discussion

Headache surgery represents a treatment option for patients with HD who have failed conservative treatment and present with symptoms indicative of nerve compression, irritation, or

M.H.J. Hazewinkel, K. Remy, L. Knoedler et al.

Table 6

Criteria for referral for surgical evaluation.

- A. One or multiple pain starting points identifiable with one finger
- B. Pain pattern corresponds to an anatomic nerve distribution both clinically and on pain drawings
- C. Injection of an anesthetic agent or botulinum toxin results in resolution or improvement of pain
- D. Failure of conservative treatment options including preventative medication, physical therapy, botulinum toxin and

nerve blocks

entrapment.^{7–10,20} However, headache surgery is currently not considered a standard therapy in the treatment algorithm for HD by non-surgical providers. This study investigated the delay of surgical treatment in patients with HD and its impact on treatment costs.

Our results demonstrate that the median duration between onset of HD symptoms and headache surgery was 20 years. Throughout this period, patients presented to multiple specialists and made numerous visits to the ED. Further, patients underwent different imaging procedures and trialed various types of conservative therapies. Overall, the mean annual cost of conservative therapy for HD was \$49,463.78 and the cost for the 20-year timeframe prior to surgery was \$989,275.65.

An important cause of this delay is the lack of awareness and knowledge of headache surgery among providers treating patients with HD. Neurologists and primary care physicians play an important role in the diagnosis and management of patients with HD as well as identifying suitable candidates for headache surgery after conservative treatments have proven ineffective. Better education regarding headache surgery for HD is required to make providers aware of this option. Screening strategies that can help non-surgical HD healthcare providers identify patients as candidates for surgery include pain drawings, nerve blocks, and botulinum toxin injections.^{19,21–23}

Patient pain drawings are a simple, readily available, and reliable tool to identify nerve pain. Patients are asked to draw where their pain starts and where it radiates. A typical pain drawing that displays nerve pain shows a focal starting point and a clear radiation pattern following the anatomical course of the affected nerve (Figure 1). It has been shown that pain drawings depicting nerve pain have good postoperative results following headache surgery.²⁴

In addition, nerve blocks can be used to identify neuropathic pain and determine which nerves are affected. A positive nerve block response (50-60% or more reduction of pain intensity after the anesthetic injection) is a reliable predictor for successful surgery.^{25,26} Further, patients who experienced a relative pain reduction lasting 24 hours or longer reported improved postoperative outcomes.²⁶ Finally, it has been shown that patients with a successful response to injection with botulinum toxin have improved outcomes following headache surgery and that botulinum toxin injections can serve as a useful diagnostic modality to screen patients for surgery.^{19,21–23}

In order to adopt surgical strategies into the treatment algorithm of HD, it is critical for establish a strong collaboration between non-surgical providers and plastic surgeons.⁶ This multidisciplinary approach ensures that patients receive conservative treatment prior to surgery and that referral for surgical management is not delayed if the patient does not respond to treatment.

To facilitate a working relationship between different providers, we have proposed a set of criteria that should prompt referral for surgical evaluation. First, patients should be able to identify one or multiple pain starting points with one finger. Second, the pain pattern (starting point and radiation pattern) should correspond to an anatomic nerve distribution both clinically and on pain drawings. Third, the injection of an anesthetic agent results in resolution or improvement of pain. Nerve block injections are the most direct and effective way to determine whether neuropathic pain is present. However, serial injections with botulinum toxin can further be used to determine candidacy for surgery. Fourth, patients have trialed conservative treatment options including preventative medication, physical therapy, botulinum toxin and nerve blocks (Table 6).

Our results demonstrate that the mean annual cost of conservative treatment for HD was \$49,463.78 per patient and that the 20-year time span between the onset of symptoms and HD surgery resulted in total costs of \$989,275.65. Direct costs accounted for 28% of the total costs, with the most significant direct expenditures attributed to nerve block administration (38%) and botulinum toxin injections (32%). Nerve blocks have not only been proven to be a reliable screening tool in HD patients, but they also carry the potential to provide long-lasting pain relief for up to several

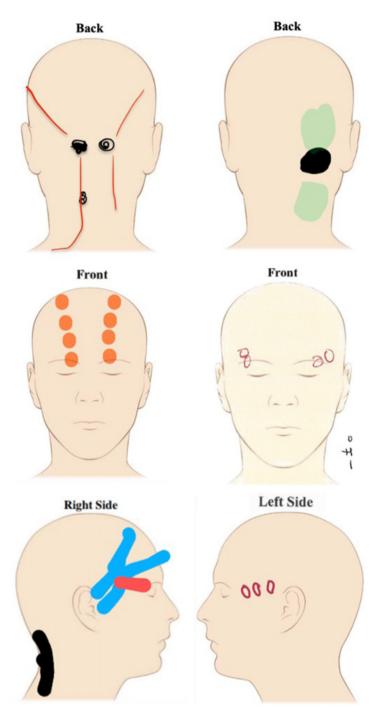


Figure 1. Typical pain drawings drawn by patients preoperatively. Upper row, occipital pain; middle row, frontal pain; bottom row, temporal pain.

months.^{25,27,28} Subsequently, nerve blocks represent a valuable therapy option for conservative treatment. Yet, our analysis revealed that this treatment approach causes substantial costs. Botulinum toxin has been demonstrated to be an evidence-based and effective long-term treatment for chronic HD patients.^{23,25} However, Schoenbrunner et al. performed a cost-effectiveness study and concluded that headache surgery is more cost-efficient than long-term botulinum toxin injections.¹⁹

The indirect cost accounted for 72% of the total cost, including presenteeism (59%), WA (27%) and LT disability (14%). It is well known that HD is associated with increased WA and reduced work productivity. Aligning with our results, previous studies report that presenteeism is more substantial than absenteeism among patients with HD.^{29–31} Regarding the economic burden of these factors, a cost analysis by Linde et al. shows that 66% of the total indirect costs of migraine were attributed to presenteeism and 33% of the total indirect costs were attributed to absenteeism, which is consistent with our findings.³²

Although we did not perform an analysis to calculate the cost associated with the treatment of postoperative HD symptoms, the literature shows a significant reduction of direct and indirect costs following headache surgery. Faber et al. performed a socioeconomic analysis of headache surgery and compared the pre- and postoperative costs of migraine headache care. The authors calculated a postoperative reduction of migraine headache treatment costs by 85%, showing that performing headache surgery leads to a tremendous reduction of direct and indirect costs.³³ Applying this percentage to our data would result in a reduction of \$42,044.21 (\$26,293.79-\$56,570.65) per year and a reduction of \$840,884.30 (\$525,875.71-\$1,131,412.89) over the 20-year time period prior to surgery.

In our study, the majority of patients reported positive surgical outcomes, which aligns with published clinical outcome research.^{12,34,35} Studies that investigated postoperative results following headache surgery reported reductions in pain frequency between 7 and 20 days, which is consistent with our observations.^{36,37} Further, recent studies examining post-surgical pain intensity have consistently shown a decrease of four to six (on a 10-point scale), mirroring our own results.³⁸ The same was true for pain duration with our group and other researchers reporting reductions of 50% or more.³⁹

It is important to interpret the findings of this study in light of its limitations. First, patients selfreported the onset of their HD symptoms which increased the risk of recall bias. Moreover, we could not calculate the cost associated with oral medication due to missing data but instead used cost estimates from a recent study of US migraineurs.⁴ Given the high prevalence of migraine medication use (95%) in our study population, the use of previously reported costs related to migraine medication was deemed appropriate for our analysis. In addition, due to insufficient data, the exact percentage of reduced productivity at work was not available. We estimated a reduced work productivity of 50% to calculate presenteeism. Finally, we were unable to control for cost inflation over the study period.

Conclusion

This study revealed that HD patients experience symptoms of HD for an average of 20 years before undergoing headache surgery. Surgical treatment not only significantly improves HD symptoms but also reduces healthcare costs.

Conflicts of interest

JJ receives royalties from Thieme and Springer Publishing. All remaining authors have declared no conflicts of interest.

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Ethical Approval

Approval was obtained from the IRB at Massachusetts General Hospital and Weill Cornell Medical Center, 2012P001527.

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