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Practice Choices and Challenges in the Current Intrathecal Therapy Environment: An Online Survey

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ABSTRACT

Objective. The objetive of this study was to evaluate current practice characteristics, treatment choices, clinical experiences, and economic concerns associated with intrathecal therapy.

Design. Health care professionals in the United States, who were known to actively use intrathecal therapy in their practices, were recruited to participate in an online survey; contact information was obtained via Internet searches, university Websites, association memberships, industry databases, and personal contacts. Survey responses were summarized descriptively.

Results. Of the 329 practitioners who were contacted, 87 participated in the survey. Most participants specialized in anesthesiology (77.0%), worked in a private practice or private hospital (74.7%), and had been practicing pain management for more than 10 years (64.4%). Morphine was the most frequently used opioid for the initiation of intrathecal therapy (80.7% of practitioners), and 81.9% had used ziconotide in their practice. Most practitioners (63.9%) had treated at least one patient who developed a granuloma, and 66.0% of those practitioners had a patient experience permanent or temporary neurological injury due to a granuloma. Fewer than half of practitioners were satisfied with reimbursement from private insurance companies (25.3%) or workers compensation (34.9%), and 90.5% believed reimbursement rates for filling, refilling, and programming patient pumps are not adequate to cover practice costs. The majority of practitioners (56.6%) use fewer pumps in their practices because of reimbursement issues.

Conclusions. Intrathecal pain management practices continue to evolve as the options for treatment increase, and the body of applicable scientific literature grows; however, economic considerations can influence clinical decisions and may interfere with treatment choice and patient access to therapy.

Key Words. Intrathecal Therapy; Pain Management; Granuloma; Reimbursement; Survey

Introduction

Intrathecal (IT) drug administration is an effective and widely accepted treatment option for patients who fail to receive adequate pain relief from less invasive methods. Despite recent additions to the published literature, many of the decisions faced in clinical practice are not adequately addressed by the available evidence-based scientific research. Practitioner survey results can identify gaps in the literature and also allow clinicians to compare their own practice choices with those of the broader community.

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A survey to assess pain practitioners' IT practices was developed to coincide with the 2007 Polyanalgesic Consensus Conference (PACC). The survey was modeled, in part, on a survey performed in conjunction with the 2000 PACC [1]. The effects of public, private, and workers' compensation insurance on IT treatment were also assessed. It is hoped that the results of this survey will reflect current clinical practice and help identify gaps in the literature that can be bridged with future research.

Methods

The current survey was authored by the program chairs of the 2007 PACC. The authors of the 2007 PACC survey reviewed and updated the 2000 PACC survey in order to assess current IT treatment practices and economic considerations. The focus of the survey conducted in 2000 was on the use of IT therapy in clinical practice, whereas the focus of the current survey was on the evolving challenges in IT therapy, specifically reimbursement. After development, the 2007 PACC survey was reviewed by five independent physicians and five laypeople for clarity and ease of understanding.

Physicians and other health care professionals in the United States who were known to actively use IT therapy in their practices were recruited for participation in the survey. Contact information was obtained via Internet searches, university Websites, association memberships, industry databases, and personal contacts. All 397 eligible practitioners were contacted via e-mail and were provided with the Website address of the survey. The target number of participants was 75, based on the response rate of the 2000 PACC survey and on research into typical response rates of other Web-based physician surveys [2–4]. Participants were offered a US$25 gift certificate as compensation for their time.

Survey questions, which were predominantly multiple-choice items, appeared consecutively on-screen. The answers were categorical in nature, and the results were summarized descriptively.

Results

Respondent Characteristics

Of the original 397 e-mails sent to eligible practitioners, 68 were returned as undeliverable. Eighty-seven of the remaining 329 practitioners participated, for an overall response rate of 26.4%.

Table 1 Characteristics of survey respondents

	Respondents, N (%)
Practice specialty	N = 87
Anesthesiology	67 (77.0)
Physical medicine and rehabilitation	8 (9.2)
Neurosurgery	5 (5.7)
Oncology	1 (1.1)
Other*	6 (6.9)
Practice environment	N = 87
Private practice, full-time pain management	56 (64.4)
Private practice, part-time pain management	5 (5.7)
Private hospital, full time	4 (4.6)
Academic, full time	19 (21.8)
Academic, part time	2 (2.3)
Other†	1 (1.1)
Years practicing pain management	N = 87
>10	56 (64.4)
5–10	17 (19.5)
2–5	11 (12.6)
1–2	2 (2.3)
<1	1 (1.1)
Pumps implanted per year	N = 86
0	2 (2.3)
1–10	32 (37.2)
11–25	29 (33.7)
26–50	15 (17.4)
51–75	5 (5.8)
76–100	2 (2.3)
>100	1 (1.2)
Pumps refilled or managed per year	N = 84
0	0 (0.0)
1–25	13 (15.5)
26–50	13 (15.5)
51–100	22 (26.2)
101–150	13 (15.5)
151–200	9 (10.7)
201–250	5 (6.0)
251–300	4 (4.8)
301–350	1 (1.2)
351–400	2 (2.4)
401–500	2 (2.4)

* Pain medicine, N = 2; pain psychology, interventional pain management, family medicine boarded full-time pain practice, and nurse practitioner (neurosurgery), N = 1 each.
† Academic, health maintenance organization.

Most participants specialized in anesthesiology (77.0%, N = 67 of 87), worked in a private practice or private hospital (74.7%, N = 65), and had been practicing pain management for more than 10 years (64.4%, N = 56) (Table 1). The majority of participants implanted 25 or fewer pumps (73.3%, N = 63 of 86) per year, and when asked how many pumps they refilled or managed each year, 26.2% (N = 22 of 84) indicated 51–100 and 15.5% (N = 13, each) selected 1–25, 26–50, and 101–150.

Clinical Questions

Neuropathic Pain and IT Drug Use

Almost 40% of practitioners indicated that the majority of their patients experience neuropathic pain (Table 2). When asked whether neuropathic

Table 2 Patient pain types* (N = 83 respondents)

Proportion of Patients (%)	Respondents, N (%)				
	Neuropathic	Nociceptive	Mixed	Cancer-Related	FBSS†
<10	3 (3.6)	3 (3.6)	0 (0.0)	57 (68.7)	3 (3.6)
11–25	20 (24.1)	26 (31.3)	11 (13.3)	19 (22.9)	27 (32.5)
26–50	27 (32.5)	31 (37.3)	28 (33.7)	1 (1.2)	24 (28.9)
51–75	25 (30.1)	17 (20.5)	29 (34.9)	3 (3.6)	26 (31.3)
>75	8 (9.6)	6 (7.2)	15 (18.1)	3 (3.6)	3 (3.6)

* Pain types are nonexclusive categories.
† Failed back surgery syndrome or postlaminectomy pain.
FBSS = failed back surgery syndrome.

pain can be effectively treated with opioids, 19.3% of practitioners (N = 16 of 83) responded "Yes," 71.1% (N = 59) chose "Sometimes," and 9.6% (N = 8) answered "No." Morphine was identified as the most frequently used opioid for the initiation of IT therapy by 80.7% of practitioners (N = 67 of 83); 18.1% of practitioners (N = 15) most often initiate IT therapy with hydromorphone, and 1.2% (N = 1) prefer sufentanil. Most respondents (81.9%, N = 68 of 83) had used ziconotide in their pain management practices. The majority of practitioners who had prescribed ziconotide (70.6%, N = 48 of 68) reported that fewer than 5% of their patients receive the drug.

Pump Refills

Approximately one-third of practitioners (34.5%, N = 29 of 84) refill their patients' pumps less frequently than they did 3 years ago; 46.4% (N = 39) indicated that the refill frequency has not changed, and 17.9% (N = 15) refill pumps more frequently (one respondent [1.2%] did not manage pump refills). When the respondents were asked what concentration of morphine they used if they refilled their patients' pumps less frequently, 6.0% (N = 5 of 84) used 10 mg/mL, 36.9% (N = 31) used 20 mg/mL, 25.0% (N = 21) used 30 mg/mL, 3.6% (N = 3) used 40 mg/mL, and 28.6% (N = 24) used 50 mg/mL.

Selecting a Compounding Pharmacy

Only a minority of practitioners (8.3%, N = 7 of 84) did not use a compounding pharmacy. Of the remainder who used a compounding pharmacy, 67.5% (N = 52 of 77) considered reputation for safety to be the most important criterion when selecting a compounding pharmacy; 20.8% (N = 16) indicated that reliable on-time delivery was most important, and drug cost and the ability to bill under assignment of benefit with commercial payers were each considered most important by 5.2% of practitioners (N = 4). One practitioner (1.3%) chose "Other."

Granuloma Formation

Fifty-three practitioners (63.9% of 83 respondents) had treated at least one patient who developed a granuloma (Figure 1). Of these 53 practitioners, 20.8% (N = 11; respondents could choose more than one answer) had an affected patient who developed permanent neurological injury, 45.3% (N = 24) had an affected patient who developed transient neurological injury, and 47.2% (N = 25) had an affected patient who did not develop any type of neurological injury. When asked what methods were used to confirm granuloma formation, 94.3% of practitioners (N = 50 of 53; respondents could choose more than one answer) had used magnetic resonance imaging, 43.4% (N = 23) had obtained a computed tomography (CT)-myelogram, 7.5% (N = 4) had used CT, and 18.9% (N = 10) had performed a sideport study. The most commonly reported methods for managing a granuloma were consultation with a neurosurgeon for granuloma removal (26.4%, N = 14 of 53 respondents), and catheter removal and replacement (24.5%, N = 13) (Table 3). None of the respondents reported having been involved in litigation because of a granuloma; however, one respondent reported a pending lawsuit.

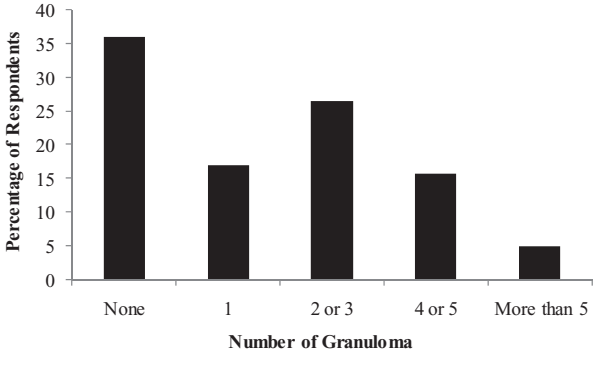

Figure 1 Number of granulomas seen in practice (N = 83).

Table 3 Methods used to manage granulomas (N = 53)

Method	Respondents, N (%)
Removed catheter	5 (9.4)
Removed and replaced catheter	13 (24.5)
Repositioned current catheter	10 (18.9)
Consulted neurosurgeon for removal	14 (26.4)
Left catheter in place and changed drug	7 (13.2)
Other	4 (7.5)

Economic Questions

Economic Considerations in IT Therapy

Most practitioners indicated that they were very involved (54.7%, 47 of 86 respondents) or somewhat involved (31.4%, 27 of 86) in the business side of their practices. Pump implantation was considered the greatest economic barrier to IT therapy by 40.5% of practitioners (N = 34 of 84); drug costs and the costs associated with pump refill procedures were considered the greatest economic barriers by 34.5% (N = 29) and 25.0% (N = 21) of practitioners, respectively. When asked to rate the importance of drug cost when prescribing an IT agent, 38.4% of practitioners (N = 33 of 86) selected "Very important," 48.8% (N = 42) chose "Somewhat important," and the remainder (12.8%, N = 11) selected "Not important." The patient's out-of-pocket cost was considered a very important factor by 65.1% of practitioners (N = 56 of 86); 26.7% of practitioners (N = 23) considered it somewhat important, and the remainder (8.1%, N = 7) considered it not important.

Reimbursement for IT Therapy

Most practitioners (83.1%, N = 69 of 83) receive reimbursement from workers' compensation for ≤25% of their pain management patients, and 67.5% (N = 56) indicated that ≤50% of their patients are covered by private insurance (Table 4). Nearly half of practitioners (47.7%, N = 41 of 86) indicated that most workers' compensation plans and private insurance companies require prior authorizations for IT administered drugs; 45.3% (N = 39) indicated that some plans require prior authorizations, and 7.0% (N = 6) reported that prior authorizations are not required by workers' compensation or private insurers. The majority of practitioners (51.2%, N = 44 of 86) did not know how often they renegotiate contracts with workers' compensation plans and private insurers. Of the remainder, 59.5% (N = 25 of 42) renegotiate every 13 to 24 months, and 40.5% (N = 17) renegotiate every 7 to 12 months. When asked whether they were satisfied with the level of reimbursement received from workers' compensation for IT therapy, four practitioners chose "N/A." Of the remainder, 45.6% (N = 36 of 79) were unsatisfied, 36.7% (N = 29) were satisfied, and 17.7% (N = 14) were unsure. When asked whether they were satisfied with the level of reimbursement received from private insurers for IT therapy, 55.4% of practitioners (N = 46 of 83) were unsatisfied, 25.3% (N = 21) were satisfied, and 19.3% (N = 16) were unsure.

More than 90% of practitioners (N = 76 of 84) believed that their practices were not adequately reimbursed for costs associated with filling, refilling, and programming patient pumps. When asked how often they bill for evaluation and management if these services are performed during a pump refill, 28.6% of practitioners (N = 24 of 84) responded "All of the time," 13.1% (N = 11) indicated "Most of the time," 40.5% (N = 34) selected "Sometimes," and 17.9% (N = 15) chose "Never." Most respondents (63.1%, N = 53 of 84) indicated that the cost of the refill kit was included in the decision for total cost reimbursement; 25.0% (N = 21) indicated that the cost of the refill kit did not enter into the decision, and 11.9% (N = 10) did not know.

The majority (64.0%) of practitioners (N = 55 of 86) indicated that between 26% and 50% of their pain management patients are insured by government payers such as Medicare (Table 4). Half of practitioners (42 of 84) did not know what type of reimbursement government payers provided for pain medications administered during IT monotherapy. Of the remainder, 40.5% (N = 17 of 42) received 95% of the average wholesale price, 33.3% (N = 14) received 100% of invoice, 16.7% (N = 7) received the average sales' price plus 6%, and 9.5% (N = 4) received invoice plus a percentage. Most practitioners (59.5%, N = 50 of 84) did not know what type of reimbursement government payers provided for combinations of pain medications administered during IT polytherapy.

Table 4 Reimbursement coverage

Proportion of Patients Covered (%)	Respondents, N (%)		
	Government Payers,* N = 86	Workers' Compensation, N = 83	Private Insurance, N = 83
1–10	1 (1.2)	37 (44.6)	1 (1.2)
11–25	8 (9.3)	32 (38.6)	19 (22.9)
26–50	55 (64.0)	10 (12.0)	36 (43.4)
51–75	17 (19.8)	0 (0.0)	19 (22.9)
76–100	0 (0.0)	0 (0.0)	3 (3.6)
Unknown	5 (5.8)	4 (4.8)	5 (6.0)

* For example, Medicare.

Of the remainder, 44.1% (N = 15 of 34) received 100% of pharmacy invoice (including the cost of the drugs and the compounding fee), 32.4% (N = 11) received 95% of the average wholesale price for each drug in the admixture, 14.7% (N = 5) received the average sales' price plus 6% for each drug in the admixture, and 8.8% (N = 3) received the pharmacy invoice plus 20%. Most practitioners would be very interested (58.1%, N = 50 of 86), or somewhat interested (26.7%, N = 23), if Medicare allowed a pharmacy to bill for IT drugs, thus eliminating all reimbursement risk to their practice; the remainder (15.1%, N = 13) would not be interested.

Impact of Reimbursement on the Use of IT Therapy

The majority of practitioners (72.1%, N = 62 of 86) indicated that reimbursement rates for IT drugs had decreased over the past 5 years; 9.3% (N = 8) reported no change, 4.7% (N = 4) indicated that reimbursement rates had increased, and 14.0% (N = 12) did not know. More than half of practitioners (56.6%, N = 47 of 83) have responded to reimbursement issues by using fewer pumps in their practices; 24.1% (N = 20) reported no change in pump use, 3.6% (N = 3) use more pumps, and 15.7% (N = 13) were unsure or responded otherwise. When asked which of the following reasons explain the reduction in pump use, 76.6% of practitioners (N = 36 of 47; respondents could choose more than one answer) cited decreased reimbursement from government payers, 46.8% (N = 22) cited decreased reimbursement from private payers, 40.4% (N = 19) cited decreased reimbursement from workers' compensation, 8.5% (N = 4) noted a change in the types of patients treated, and 40.4% (N = 19) indicated a preference for alternates based on observed outcomes.

Future Direction of Reimbursement and the Impact on the Use of IT Therapy

Most practitioners (71.1%, 59 of 83) expected drug reimbursement to worsen over the next 5 years; 10.8% (N = 9) anticipated little change, 4.8% (N = 4) expected reimbursement to improve, and 13.3% (N = 11) did not know. Given reimbursement trends over the past 3 years, 44.2% of respondents (N = 38 of 86) anticipated implanting and/or managing fewer IT pumps in the future, 43.0% (N = 37) expected the number to remain about the same, 11.6% (N = 10) expected the number to increase, and 1.2% (N = 1) did not expect to implant and/or manage any IT pumps in the future.

Discussion

The results displayed here and those from a survey published in 2000 [1] suggest that morphine remains the drug of choice for initiation of IT therapy. Physicians who responded to the 2000 survey indicated that 87% of their patients received morphine alone during a trial of IT therapy, and 80.7% of respondents to the current survey choose morphine over other opioid analgesics for initiation of IT therapy. The 2000 survey also revealed that a smaller proportion of physicians would initiate IT therapy with morphine alone for a patient with neuropathic pain (72%) than for a patient with somatic nociceptive pain (87%), suggesting that physicians were less confident about the effectiveness of morphine for neuropathic pain than for other pain syndromes. In the current survey, 80.7% of practitioners believed that opioids were ineffective, or only sometimes effective, for treatment of neuropathic pain. More than 80% of practitioners who responded to the current survey had used ziconotide, a non-opioid IT analgesic, in their practices. Ziconotide is recommended as a first-line therapy in the 2007 PACC algorithm for IT drug selection [5]. The 2007 PACC also reviewed several experimental IT medications, some of which show promise for the treatment of neuropathic pain [6].

Granulomas are a rare but potentially devastating complication associated with IT therapy. Most practitioners in the current survey (63.9%) had treated at least one patient who developed a granuloma; among these practitioners, 66.0% had a patient who experienced neurological injury due to a granuloma. The circumstances that lead to granuloma formation are not well understood, but delivery of high doses or concentrations of opioids may increase patient risk [7–9]. Notably, more than half of practitioners (57.1%) have prescribed morphine in concentrations that exceed the maximum concentration recommended by the 2007 PACC (20 mg/mL) [5]. An expert panel from the 2007 PACC has published guidelines for the prevention and management of granulomas [10].

Responses to the series of economic questions reveal that practitioner concerns about cost and reimbursement issues influence treatment choices and practices. Most respondents (87.2%) considered drug cost to be an important or somewhat important consideration when prescribing an IT analgesic. The majority of practitioners (72.1%) indicated that reimbursement rates for IT drugs had decreased over the past 5 years, and a similar

proportion (71.1%) expects drug reimbursement to worsen in the future. In addition, more than 90% of respondents believed that reimbursement rates do not adequately cover the cost of filling, refilling, and programming patient pumps. Such economic considerations appear to be negatively affecting the use of IT therapy, with 56.6% of respondents using fewer pumps in their practices because of reimbursement issues.

Although the results of this survey provide insight into the challenges of IT therapy, analyses that included demographic considerations were limited because of the uneven distribution of these parameters. For example, most respondents (77.0%) specialized in anesthesiology and most (70.1%) were in private practice. In future surveys, the role of demographic parameters on practice choices should be considered. Such analyses may provide a better understanding of the current use of IT therapy.

Conclusions

Considerable progress has been made in the field of IT therapy since the 2000 PACC survey. Ziconotide was approved by the United States Food and Drug Administration in 2004, making it the first new IT analgesic in more than a decade to gain such approval. IT drug selection algorithms developed by the 2000 and 2003 PACCs have aided physicians in choosing the safest and most effective drugs for their patients, a trend that has continued with the publication of the 2007 PACC algorithm [5]. Strides have also been made in the prevention and treatment of granulomas. Despite these and other advances, results of the current survey suggest that economic and reimbursement difficulties are limiting the use of IT therapy. Considering the current economic environment, reimbursement issues will likely continue to be a challenge for clinicians and patients. Additional studies are needed to further evaluate the effects of economic trends on patient access to this valuable treatment modality.

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