의학석사 학위논문

Retrospective Analysis of the Intrathecal Morphine Pump Use after Insurance Benefits: Focused on Economic Efficiency

보험 급여 적용 후 척수강 내 모르핀 펌프에 대한 후향적 분석: 경제적 효율성을 중심으로

2017 년 8 월

서울대학교 대학원

의학과 마취통증의학 전공

김은경

A thesis of the Degree of Master of Philosophy

보험 급여 적용 후 척수강 내 모르핀 펌프에 대한 후향적 분석:

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Eunkyoung Kim

Retrospective Analysis of the Intrathecal Morphine Pump Use after Insurance Benefits: Focused on Economic Efficiency

By

Eunkyoung Kim

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Professor _____Chairman

Professor _____Vice chairman

Professor _____

보험 급여 적용 후 척수강 내 모르핀 펌프에 대한 후향적 분석:

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지도교수 김용철

이 논문을 의학석사 학위논문으로 제출함

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김은경의 의학석사 학위논문을 인준함

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위 원 장 _____

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위 원 _____

Abstract

Introduction: The aims of this study were to investigate the financial break-even point (FBEP) and patients' satisfaction in patients who received IntraThecal Morphine Pump (ITMP) implantation after the initiation of the Korean National Health Insurance (KNHI) reimbursement policy in Korea.

Method: We collected data through retrospective database analysis and direct phone calls to patients who underwent ITMP implantation at the Seoul National University Hospital (SNUH) Pain clinic between July 2014 and May 2016. Pain severity, changes in the Morphine Equivalent Daily Dosage (MEDD), any adverse events associated with ITMP implantation, and patients' satisfaction were determined. In addition, we calculated the FBEP of ITMP in patients via investigating the patient's actual medical costs and insurance information.

Results: During the period, 23 patients received ITMP implantation at SNUH, and 20 patients were included in our study. An 11-point NRS pain scores were significantly reduced compared to the baseline value ($P < 0.001$). The median intrathecal MEDD before ITMP implantation was 0.59 [IQR: 0.55-0.82]. Throughout the follow-up period, the total MEDD increased steadily to 0.77 [IQR: 0.53-1.08] at 1 year which was 126% of baseline ($P < 0.001$). More than a half (60%) responded that the ITMP therapy was somewhat satisfying and 16 patients (80%) agreed that the ITMP helped to control their pain. The FBEP was 28 months for ITMP implantation treatment after the KNHI reimbursement policy.

Conclusions: In conclusion, ITMP provided effective chronic pain management with improved satisfaction and reasonable FBEP of 28 months with 50% financial coverage by KNHI program.

Keywords: chronic pain; financial break-even point; intrathecal pump; morphine equivalent dosage; reimbursement policy; and satisfaction.

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Introduction

Chronic pain is a major public health issue affecting 20% of the adult population worldwide [1-3]. The personal and socioeconomic effects of chronic pain are considered to be at least as great as those of other established healthcare priorities, including cardiovascular disease and cancer [4]. Although it impacts quality of life in multiple functional domains, including family life, workplace performance, social interactions, and sleep patterns [1, 2], less than 2% of chronic pain patients have access to a comprehensive specialist pain clinic [5, 6]. The Declaration of Montreal states that pain management is inadequate across most of the world (IASP, 2012).

Patients with chronic, intractable pain may benefit from interventional strategies such as intrathecal morphine pump (ITMP) [2]. The intrathecal (IT) administration of opioid medications through ITMP permits the delivery of higher drug concentrations into the cerebrospinal fluid with lower concentrations reaching the systemic circulation [7]. This direct action of analgesics at spinal receptors accompanied by reduced drug delivery to the brain via the blood-brain barrier may provide clinical benefits with lower risks of adverse effects compared to systemic opioid therapy [8, 9]. Therefore, although relegated to one of the interventions of '*last resort*', ITMP should be considered to improve pain control, optimize patient functionality, and minimize the use of systemic pain medications in appropriately selected patients with refractory chronic pain [10].

Despite these advantages, the substantial costs that arise at the time of surgical implantation (US$ 16,000 in Korea to US$ 35,000 in the USA) and difficulties with reimbursement continue to negatively affect ITMP use [11]. In Korea, the high cost of ITMP implantation is the main obstacle to its use-except in extremely rare cases. However, since July 2014, the Korean National Health Insurance (KNHI) program began financially supporting 50% of the ITMP implantation cost in select refractory chronic pain patients. Currently, Korean government reimbursement is approved for patients with the following conditions: long-term severe pain (persistent numerical rating scale [NRS] pain score ≥ 7), insufficient

pain control for 6 months when using other analgesic methods, patient life expectancy > 1 year, and cancer pain that is unresponsive to high doses of oral morphine or an equivalent dose of other narcotic analgesics.

A previous study in eleven patients with non-cancer pain and one cancer patient that underwent ITMP therapy in Korea indicated that the median time required to reach the financial break-even point (FBEP) was 24.2 months [12]. The new KNHI reimbursement policy may promote wider use of ITMP as a treatment option for chronic pain patients in Korea, which would affect the FBEP in Korean patients. Therefore, this study was performed to investigate the FBEP in patients receiving ITMP implantation since July 2014 after the initiation of the KNHI reimbursement policy and to assess patient satisfaction.

Materials and Methods

This retrospective study was approved by the institutional review board (IRB) of Seoul National University Hospital (SNUH; IRB No. H-1601-053-733). Upon IRB approval, we identified patients that received ITMP implantation between July 2014 and May 2016 at the department of Anesthesiology and Pain Medicine of SNUH. We performed a retrospective database analysis that weighted the pre-implantation and post-implantation claims for ITMP costs and surveyed patients by in-person phone calls to evaluate the average level of satisfaction after implantation. The requirement for written informed consent was waived by SNUH's IRB.

Data was extracted from patients' electronic medical records, the operative reports, and the medical progress notes. We included demographic and clinical characteristics of the patients such as age, gender, height, weight, pain duration, diagnosis, prior surgical history, and underlying diseases (diabetes mellitus and concomitant psychopathologies).

Pain severity using an 11-point NRS pain score was determined by a retrospective review of the patient's electronic medical records before ITMP as a baseline score and for 1 year after ITMP implantation. Changes in the morphine equivalent daily dosage (MEDD) before and after ITMP implantation were also investigated, including all opioid medications administered orally, intrathecally, and/or transdermally.

Escalation in daily opioid dosage was investigated over a 1-year period after ITMP implantation in each patient. In addition, concomitant around-the-clock and/or *pro re nata* analgesics other than strong opioids, including non-opioid/weak opioid analgesics such as tramadol, acetaminophen, and non-steroidal anti-inflammatory drugs, were reviewed. Interventional procedures or conservative treatments other than analgesic medications for managing pain were also assessed. Any complications associated with the ITMP, including constipation, nausea, vomiting, urinary retention, dizziness, dry mouth, and diaphoresis, were thoroughly reviewed. The patients' overall satisfaction following ITMP implantation was surveyed at one year via a phone call and rated on a five-point Likert scale from "extremely satisfied" to "extremely dissatisfied." We then surveyed the patients regarding their overall recommendations to

improve the device.

Financial information was obtained from the data processing department (DPD) and insurance review department (IRD) of SNUH. In addition, the IRD provided data about each participant's type of insurance coverage. Actual payments for the entire medical services for 6 months before ITMP implantation, consistent with the reimbursement policy of the KNHI program, and for one year after the implantation were calculated. Payments for medical services performed at facilities other than SNUH were not included in this study. Average medication costs (e.g., oral medication and patches) were investigated at three pharmacies close to SNUH.

The DPD provided the actual costs paid by each patient before, during, and after ITMP implantation, which included the costs for all medical services performed at SNUH. The total cost prior to ITMP implantation included the costs of medical services, interventions, procedures, and medications for 6 months before ITMP implantation. The total cost after ITMP implantation included outpatient medical costs, analgesics for breakthrough pain, and ITMP refills for one year after the ITMP implantation. With regard to the total implantation cost, each patient's actual payment for the ITMP implantation procedure, including hospitalization, was calculated. The total cost of medical services during the treatment period, expressed in Korean Won (KRW)/day, was divided into pre- and post-ITMP implantation segments to determine the FBEP.

NRS pain scores and the daily costs before and after ITMP implantation were compared. Each patient's total payment of medical costs for ITMP implantation divided by the difference between the costs per day before and after the ITMP implantation was used to define the FBEP. Difference between two time-points were analyzed using paired *t*-test or Wilcoxon signed rank test for continuous variables with a normal or non-normal distribution, respectively. Statistical analyses were performed using SPSS version 20.0 (IBM Corp., Armonk, NY). The data are expressed as median values [Interquartile range (IQR)]. In all analyses, $P < 0.05$ was taken to indicate statistical significance.

Results

Twenty-three patients received ITMP implantation with a Medtronic SynchroMed II® pump (Medtronic, Inc., Minneapolis, MN) at SNUH between July 2014 and May 2016 (**Figure 1**). All surgical procedures for ITMP implantation were performed by one pain specialist (Y. C. K). Three patients were excluded from the study for the following reasons: one patient received ITMP implantation with baclofen, one patient received a replacement ITMP following the first ITMP implantation in 2008, and one patient was mainly managed at another hospital and only visited SNUH for ITMP treatment. Therefore, 20 patients were included in the study. The demographic characteristics of the patients are shown in **Table 1**. All patients were implanted with ITMP for the management of chronic non-cancer pain. The most common diagnoses for ITMP therapy in patients with chronic non-cancer pain were complex regional pain syndrome (n = 7) and failed back surgery syndrome (n = 7), followed by fibromyalgia (n = 2), post-traumatic pain syndrome (n = 4). The median pain duration before ITMP implantation was 63 months [IQR: 38-91].

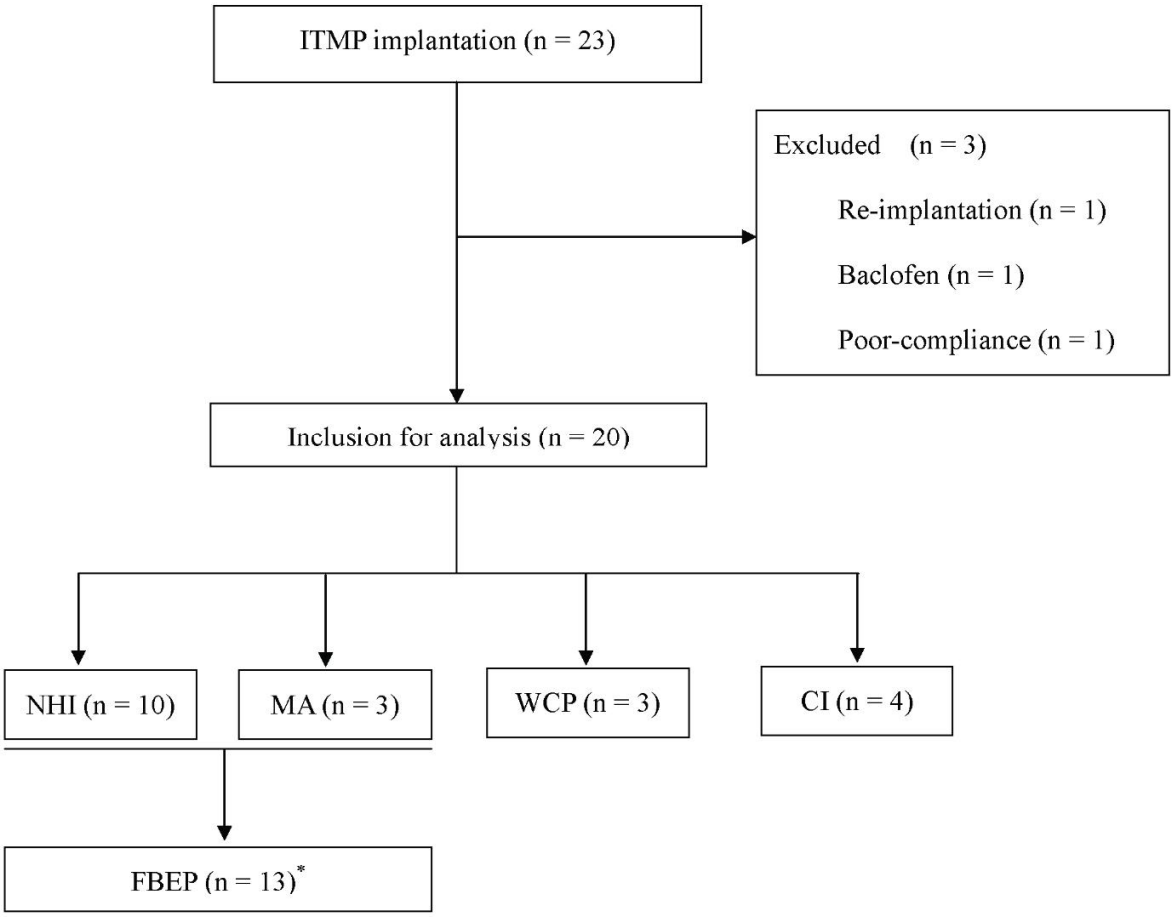

Figure 1. Flowchart

*Thirteen patients that received 50% benefits from the new KNHI policy were included to calculate the financial break-even point.

NHI = Korean national health insurance; MA = medical aid; WCP = worker's compensation plans; CI = car insurance; and FBEP = financial break-even point.

Table 1. Demographics

No.	Gender	Age (y)	BMI (kg/m^2)	Duration of pain (month)	Diagnosis	Baseline NRS pain score	Insurance type
1	M	41	18.2	63	FBSS	10	KNHI
2	M	28	29.0	111	FM	10	KNHI
3	M	54	27.7	58	FBSS	8	KNHI
4	M	61	23.5	63	PTPS	9	KNHI
5	F	70	24.4	37	PTPS	10	KNHI
6	F	37	23.6	17	CRPS II	10	KNHI
7	M	59	25.5	71	FBSS	8	KNHI
8	M	76	25.8	187	PTPS	10	KNHI
9	M	75	26.0	63	FBSS	9	KNHI
10	F	74	21.3	195	FBSS	10	KNHI
11	F	44	20.7	38	CRPS I	10	MA
12	F	55	29.1	104	FBSS	10	MA
13	M	43	29.0	52	CRPS II	10	MA
14	M	53	26.1	86	CRPS I	9	WCP
15	M	52	25.8	81	CRPS I	9	CI
16	M	42	28.5	16	CRPS I	10	CI
17	M	31	41.8	46	CRPS II	10	CI
18	M	54	27.9	33	FM	9	CI
19	M	46	21.2	126	PTPS	9	WCP
20	M	47	25.2	24	FBSS	10	WCP
Median (IQR)		53 (43.0-60.0)	25.8 (23.6-28.1)	63 (38.0-91.0)		10 (9.0-10.0)	

FBSS = failed back surgery syndrome; FM = fibromyalgia; PTPS = posttraumatic pain syndrome; CRPS = complex regional pain syndrome; KNHI = Korean national health insurance; MA = medical aid; WCP = worker's compensation plans; CI = car insurance; y = year; mon = month; and IQR = interquartile range

Figure 2 shows the changes in the 11-point NRS pain score between pre- and post-implantation. The baseline median NRS pain score was 10 and ranged between 8 and 10. The value decreased to within the range of 0 to 8 with a median score of 6 at 1 week; all patients (n = 20) responded that their pain had decreased by more than 2 of 10 points after ITMP implantation. Although the NRS pain score increased steadily for 1 year after ITMP implantation, the median NRS pain score was still reduced relative to the baseline at 12 months, with a median score of 5, ranging from 3 to 8. Eighteen patients (80%) still showed a reduction of ≥ 2 points in their NRS pain score at 1 year. The NRS pain scores at each follow-up point were significantly reduced compared to the baseline value before ITMP implantation ($P < 0.001$ between the baseline score and score at each follow-up point).

The median IT MEDD before ITMP implantation was 0.59 [IQR: 0.55-0.82] (**Figure 3**). The median initial setting of IT dosage via ITMP was 0.47 mg/day [IQR: 0.44-0.65], which was 70–90% of the previous MEDD in each case at the discretion of the physician. In addition, patients received a concurrent immediate release form of opioid; therefore, the total MEDD at 1-week follow-up, calculated as IT administration was 0.61 [IQR: 0.46-0.82]. Throughout the follow-up period, the MEDD was increased steadily to 0.60 [IQR: 0.47-0.88] as IT administration via ITMP and 0.77 [IQR: 0.53-1.08] at 1 year as the total MEDD, representing a 126% of baseline ($P < 0.001$ for both IT and total administration).

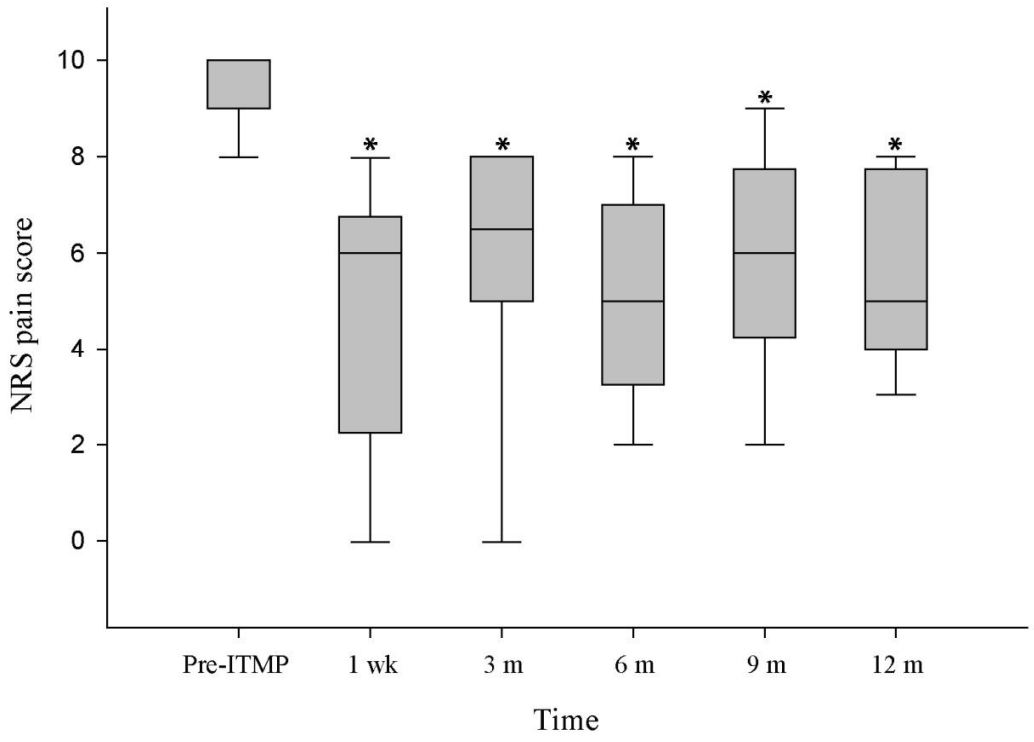

Figure 2. Numeric rating scale (NRS) pain scores from pre-implantation to 12 months after implantation. The box plot shows a set of three quartiles and the maximum and minimum graphically. At Pre-ITMP and 3 months, the maxima are not displayed because they were same as the median 3rd quartile and the 3rd quartile, respectively.
*Statistically significant difference between the time point and Pre-ITMP ($P < 0.05$).
wk = week; and m = month

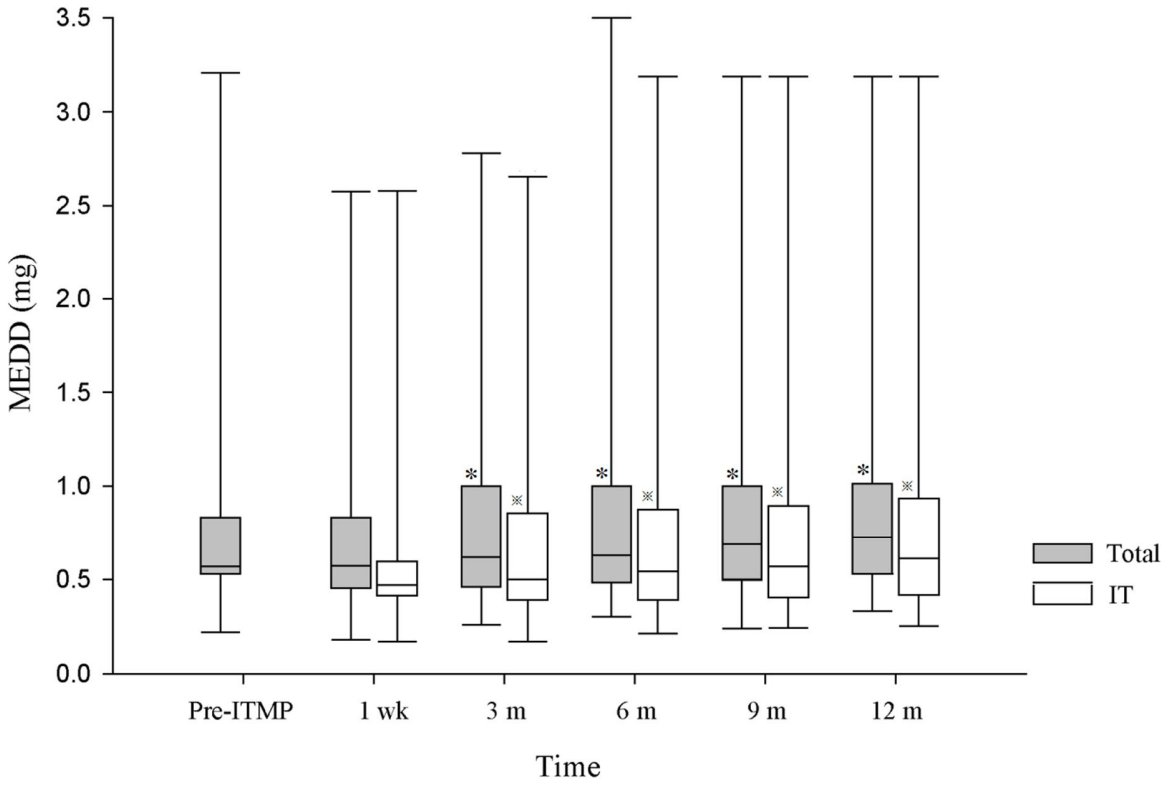

Figure 3. Daily intrathecal morphine equivalent drug doses (MEDD) at various time points. The box plot shows a set of three quartiles and the maximum and minimum graphically.

*Statistically significant difference between the initial total morphine dose and each time point ($P < 0.05$). The total morphine dose is calculated by converting the amount of morphine entering the patient's intrathecal (IT) and all other routes into the amount of morphine entering the IT.

※Statistically significant difference between the total IT morphine dose as the initial setting and each time point ($P < 0.05$).

wk = week; and m = month

The 20 patients included in the analysis were surveyed by an in-person phone call and asked about their overall satisfaction after the ITMP implantation treatment using a 5-point Likert scale. Twelve patients (60%) responded that it was somewhat satisfying, four patients (20%) responded that they were 'neither satisfied nor dissatisfied' with ITMP management, two patients (10%) were 'completely dissatisfied', and two patients refused to answer the question (**Figure 4**). Patients that were 'completely dissatisfied' also complained of severe worsening of pain accompanied by neuropsychiatric panic disorders such as panic or depressive disorders. Nonetheless, all patients agreed that the frequency and intensity of their pain had been alleviated. Sixteen patients (80%) also agreed that the ITMP helped to control pain. Finally, when we surveyed patients about their recommendations to improve the device, most patients (n = 16, 80%) suggested that a reduction in the pump reservoir size and the acquisition of a controlling device for self-infusion (patient-controlled analgesia) would improve general satisfaction and pain control. A personal therapy manager (myPTM™; Medtronic, Inc.) was not available before November 2016 in South Korea.

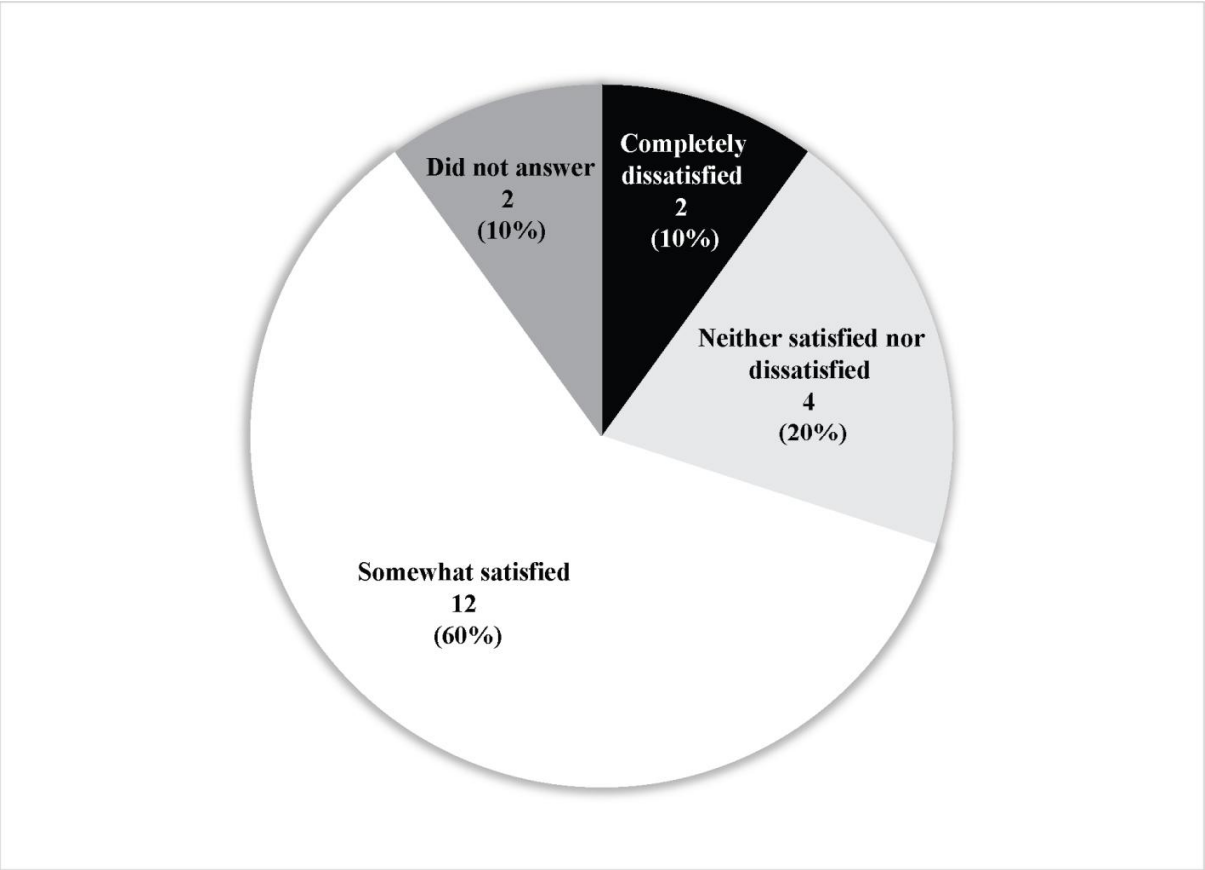

Figure 4. Overall satisfaction after intrathecal morphine pump (ITMP) implantation treatment using a 5-point Likert scale. One year after the ITMP implantation, we interviewed twenty patients by phone call directly and asked for satisfaction with the ITMP therapy. Of the 18 patients who answered, twelve (60% out of 20 patients) responded 'somewhat satisfied', four (20%) answered 'neither satisfied nor dissatisfied', and two (10%) 'completely dissatisfied'. None of the patients answered 'somewhat dissatisfied' and 'completely satisfied'.

Table 2. Adverse events observed after ITMP implantation. Adverse events between initial visit and after 12 months were not statistically significant. There were no serious life-threatening side effects, and the number of people without side effects was 10 (50%) in the initial visit and 12 60%) in the after 12 months.

	Initial visit (%)	After 12 months (%)
Dysuria	3 (15)	1 (5)
Nausea	2 (10)	1 (5)
Vomiting	1 (5)	0 (0)
Gastric discomfort	2 (10)	2 (10)
Constipation	2 (10)	1 (5)
Somnolence	2 (10)	0 (0)
Dizziness	1 (5)	1 (5)
Dry mouth	1 (5)	1 (5)
Skin eruption	0 (0)	0 (0)

Itching	0 (0)	0 (0)
Anorexia	1 (5)	0 (0)
Edema	0 (0)	0 (0)
Sweating	0 (0)	1 (5)
Headache	0 (0)	0 (0)
No side-effects	10 (50)	12 (60)

The side effects observed after ITMP implantation are shown in **Table 2**. At one week after ITMP implantation, half of the patients reported one or more adverse events associated with ITMP implantation; dysuria (n = 3) was the most frequent event, followed by nausea, vomiting, and gastric discomfort. Ten patients reported that they had not experienced any adverse events related to ITMP. At one year, twelve patients were free from opioid-related side effects.

To calculate the FBEP, we investigated each patient's reimbursement insurance status (shown in **Table 1**). Among the 20 patients in this study, 10 (50%) were reimbursed by KNHI coverage. Three patients (15%) were under Medical Aid (MA) as an extension of the KNHI program for minorities. Among the remainder, three patients were covered by Worker's Compensation Plan Insurance (WCPI) and four patients were under Car Insurance (CI) coverage. KNHI paid 50% of ITMP costs and MA covered 50% of ITMP costs and partial professional fees. WCPI and CI covered 100% of ITMP costs. The actual total ITMP cost of the patient's share of medical costs differed markedly according to the type of insurance, and ranged from 0 to 8580000 KRW. Therefore, to estimate the FBEP, we included only thirteen patients in the study who paid for 50% of their actual ITMP costs; ten were covered by KNHI and three had MA coverage. Their FBEP are shown in **Table 3**. Their pre-implantation medical costs ranged between 6011 and 41129 KRW/day (median: 10905 KRW/day). The post-implantation medical cost per day ranged between 902 and 11178 KRW/day (median: 3461 KRW/day). It has been shown that the cost of medical care per day after ITMP implantation is significantly lower than the cost per day before implantation ($P < 0.001$). Our data show that a period of 28 months was required to reach the FBEP following ITMP implantation treatment.

Table 3. Analysis of the cost effectiveness of ITMP treatment

No.	Total ITMP* (KRW)	Pre-ITMP		Post-ITMP		Pre-Post† (KRW/d)	FBEP†† (mon)
		Cost (KRW)	KRW/d**	Cost (KRW)	KRW/d**		
1	7,960,000	1,250,000	19,531	600,000	1,863	17,668	15
2	7,910,000	2,170,000	10,905	2,320,000	6,535	4,369	60
3	8,080,000	1,290,000	7,544	1,540,000	3,461	4,083	66
4	7,990,000	1,100,000	6,011	1,360,000	3,170	2,841	92
5	8,080,000	950,000	38,000	2,170,000	6,382	31,618	8
6	8,580,000	3,340,000	21,274	4,270,000	11,178	10,096	28
7	8,000,000	2,150,000	12,356	1,220,000	3,089	9,268	27
8	8,050,000	820,000	9,213	830,000	2,594	6,620	40
9	7,950,000	980,000	15,806	2,360,000	6,592	9,214	28
10	8,190,000	1,990,000	10,000	1,510,000	3,963	6,037	45
11	7,810,000	1,840,000	10,337	1,810,000	5,142	5,195	50
12	7,610,000	5,100,000	41,129	970,000	2,803	38,326	6
13	5,260,000	1,170,000	10,636	350,000	902	9,734	18
Median	7,990,000	1,290,000	10,905	1,510,000	3,461	9,214	28
(IQR)	(7,910,000-8,080,000)	(1,100,000-2,150,000)	(10,000-19,531)	(970,000-2,170,000)	(2,803-6,382)	(5,195-10,096)	(18-50)

*The cost actually paid for ITMP implantation under Korean national health insurance coverage.

**The cost paid for pain management per day.

†Difference in the pain management cost per day between before and after ITMP implantation.

††The cost of conventional medical management exceeded that of intrathecal drug pump therapy within the period expressed as the financial break-even point.

ITMP = intrathecal morphine pump; FBEP = financial break-even point; KRW = Korean Won; KRW/d = Korean Won per day; mon = month; and IQR = interquartile range

Discussion

Chronic pain is acknowledged as a condition in its own right that results in both physical and emotional burdens on patients as well as a huge financial cost to society (currently estimated at more than €200 billion per annum in Europe and $150 billion per annum in the USA) [13]. Economic and reimbursement difficulties continue to constrain the use of advanced therapies such as ITMP implantation for chronic pain patients [14]. Studies evaluating the cost-effectiveness of ITMP implantation may encourage organizations to reduce costs or to increase health insurance coverage, and it may promote the use of this expensive therapy. Therefore, we performed a retrospective study to analyze the influence of Korea's reimbursement policy, adopted in 2014, with regard to the FBEP for ITMP in chronic non-cancer pain patients at SNUH, trends in patient access to this treatment, and patients' overall satisfaction.

With regard to the efficacy of ITMP, 80% (n = 18) of the patients in our study showed a reduction of ≥ 2 points in their NRS pain score at 1 year after ITMP implantation, and the other two patients showed a decrease of 1 point in their NRS pain score compared to the pre-implantation score. Although the results of previous studies were contradictory with regard to the efficacy of ITMP use in chronic non-cancer and cancer pain patients, recent research by Hamza et al. strengthened the positive results reported for ITMP treatment (94% of non-malignant pain patients showed > 26% improvement in their pain score compared with the baseline) [15]. In our study, we also found a reduction in NRS pain score at the initial and final follow-up visits compared to the baseline score before ITMP implantation. We suggest that appropriate patient selection is the key to a successful outcome following ITMP treatment [16].

Increasing IT opioid administration, which was reported in previous studies, indicates that dose escalation may be independent of the opioid delivery method over the long term [17-20]. In

our study, the MEDD escalation was statistically significant, and researchers generally describe the escalation in MEDD to achieve the same analgesic effect as drug tolerance. Several articles have attempted to explain the mechanism of this phenomenon, and one author has argued that technical problems with ITMP could cause tolerance [16, 21]. Some authors have attempted to predict the occurrence of this resistance and have identified diagnosis, individual genotypes, and other factors as predictors of opioid dose escalation [22]. It has been shown that the biological characteristics of individuals determine the mechanism of pain generation, symptoms, and responses to drugs [23], and we anticipate that the development of these genetic studies will reduce treatment failures by individualized treatment.

In this study, the increase in median IT dosage was 126% at the first year of follow-up compared to the initial IT dosage. This rate of increase was relatively low compared to those suggested in a systematic review by Turner et al., which indicated a 2.6-7.4-fold increase in IT opioid dosage from initial levels at 24 months [17]. However, this was similar to the results of our previous study performed at the same hospital indicating that the IT dose escalation was 136.9% during the first year [12]. We assume that a lower initial IT dose may have been related to the decreased IT escalation rate in our study, which may support previous studies suggesting that using a low-dose IT opioid trailing method had clinical benefit as an effective dosing strategy [24, 25].

With regard to satisfaction with ITMP treatment, 63% of patients were ‘somewhat satisfied’ with their ITMP therapy. This was an improvement in comparison with our previous study that showed that only 41% of patients were ‘somewhat satisfied’ prior to KNHI reimbursement [12]. Although, 20% of the patients in our study responded that they were ‘neither satisfied nor dissatisfied’ and 10% did not respond, all patients agreed that the frequency and intensity of their pain had been decreased and eased. The large size of the pump was one of the main issues to be

addressed in the future. Patients generally felt uncomfortable with the pump device when wearing thin clothes, while lying down, or sitting straight. Therefore, future ITMP development should include reducing the size of the device.

Prior to July 2014, Korean patients were required to pay all costs related to ITMP implantation with their own money. However, since the Korean reimbursement system was announced in July 2014, 50% of ITMP costs can be reimbursed to patients that fulfill the established criteria of the KNHI program. This implies a huge economic benefit to patients considering ITMP treatment; however, there may be concerns about the inappropriate application of ITMP treatment. In the present study, when patients paid their medical costs using KNHI coverage, it took 28 months to obtain a financial advantage. Although this is somewhat longer than the period of 24.2 months that we reported in a previous study without KNHI coverage [12], it is still worthwhile when taking into account that the median longevity of patients with ITMP use is 5.4 years (95% confidence interval: 5.0–5.8) [2]. Studies in the USA have reported cost-effectiveness data for ITMP treatment, with a diverse range from 7.6 months in cancer patients to 22 months for patients with non-malignant pain [26]. As we did not administer the concept of quality-adjusted life years in our analysis of cost effectiveness and did not include costs paid to other hospitals, it is not possible to compare our results with previous cost-effectiveness data. However, when we consider that the overall medical service fee is much cheaper in Korea than in the USA and if we reflect on the benefits from the improvement in quality of life, the FBEP of 28 months in our study is not excessive.

In South Korea with the new insurance policy, a wider range of patients gained access to ITMP therapy. According to the data provided by Medtronic, Inc., 109 ITMP implants were performed for two years after the introduction of the insurance system (2014-2016), but only 81 ITMP implants were performed during the six years prior to the introduction of the insurance

(2008 – 2014). In a previous study, 12 of 19 patients who were treated for 6 years between 2008 and 2014 were analyzed for cost [12], and this study was performed for 13 of 23 patients who were treated for two years between 2014 and 2016 . There was no difference in the survey method between the two papers. Patients who meet the KNHI-declared criteria are more likely to receive ITMP transplants than before, and the patients' median economic break-even point for ITMP therapy has been lengthened despite insurance coverage. However, the statistically significant decrease in post-ITMP cost per day suggests that ITMP therapy has an economic benefit to the patient. In addition, the fact that the FBEP is shorter than the longevity of the pump can lead to the conclusion that if the patient maintains ITMP therapy for longer than the longevity of the pump, then ITMP therapy is more economical for the patient than conventional medical therapy. And a significant reduction in Post-NRS pain score can be interpreted as ITMP treatment contributing to the patient's effective pain reduction.

Since our study is a retrospective analysis, there is no control. However, the patients we analyzed were chronic pain patients with a median value of more than 5 years. In these chronic pain patients, the pain rarely disappears spontaneously. We performed the epidural morphine test before permanent insertion for the success of the ITMP procedure, and performed the ITMP permanent implant only if the effect was confirmed and the patient agreed. Therefore, regression to the mean bias can be ruled out.

There are several limitations to this study. First, this was a retrospective study, and our results may have been affected by characteristic confounders, including bias and variability in the quality of available information. Second, as mentioned previously, the concept of improvement in quality of life was not administered in our analysis. Furthermore, we did not include pharmaceutical and non-pharmaceutical treatment costs at other institutions. These may reduce the time needed for the FBEP, which was suggested in this study as 28 months. Finally, this was a

single-center study with a limited number of patients, which would result in several biases related to patient selection for ITMP treatment or medical costs other than ITMP treatment. Future prospective large cohort studies should attempt to validate the cost effectiveness of ITMP therapy.

In conclusion, ITMP provided effective chronic pain management with overall improved satisfaction and fewer systemic adverse events in our study. The FBEP was 28 months in patients with 50% coverage of their medical cost for ITMP implantation by the KNHI program. When we, as pain physicians, consider the application of ITMP therapy for the management of intractable chronic cancer or non-cancer pain, attention should be paid to appropriate patient selection as well as their clinical improvement and economic benefits. Additional studies are required to improve patients' pain and analyze the cost effectiveness of ITMP management.

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국문 초록

서론: 본 연구의 목적은 한국의 척수강 내 모르핀 펌프 이식술을 받는 환자에 대한 국민 건강 보험 정책 시작 후 척수강 내 모르핀 펌프 이식을 받은 환자들의 재정적 손익 분기점과 환자 만족도를 조사하는 것이다.

방법: 2014년 7월에서 2016년 5월 사이에 서울대학교병원 통증 클리닉에서 척수강 내 모르핀 펌프 이식을 받은 환자들을 대상으로 후향적인 의무기록 분석과 개별 전화 통화를 통해 통증의 강도, 모르핀의 등가 1일 용량의 변화, 척수강 내 모르핀 펌프 이식과 관련된 부작용 및 환자 만족도에 대한 자료를 수집했다. 또한 환자의 실제 의료 비용 및 보험 정보를 조사하여 척수강 내 모르핀 펌프의 재정적 손익 분기점을 계산하였다.

결과: 해당 기간 동안 서울대학교병원에서 23명의 환자가 척수강 내 모르핀 펌프 이식을 받았고 20명의 환자가 본 연구에 포함되었다. 숫자 통증척도는 기준치와 비교하여 유의하게 감소하였고 ($P < 0.001$), 척수강 내 모르핀 펌프 이식 전의 모르핀 등가 1일 용량의 중앙값은 0.59였다 [IQR: 0.55-0.82]. 1년간의 추적 관찰 기간 동안 총 모르핀 등가 1일 용량은 기준선의 126%까지 지속적으로 증가하였다 ($P < 0.001$). 60%의 환자가 척수강 내 모르핀 펌프 이식에

대해 다소 만족한다고 응답했으며 80%의 환자는 척수강 내 모르핀 펌프 이식이 통증조절에 도움이 된다고 응답하였다. 척수강 내 모르핀 펌프에 대한 재정적 손익분기점은 28개월로 조사되었다.

결론: 척수강 내 모르핀 펌프는 효과적인 만성통증 관리를 제공하여 국민 건강 보험 정책에 의한 50%의 재정적 보상으로 28개월이라는 합리적인 재정적 손익분기점 및 환자 만족도의 개선을 이끌어냈다.

주요어: 만성통증; 손익분기점; 척수강 내 펌프; 모르핀등가1일용량; 보험정책; 환자만족도

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Abbreviation, Tables, and Figures

CI	car insurance
CRPS	complex regional pain syndrome
DPD	data processing department
FBEP	financial break-even point
FBSS	failed back surgery syndrome
FM	fibromyalgia
IASP	International Association for the Study of Pain
IBM	International Business Machines Corporation
IQR	interquartile range
IRB	institutional review board
IRD	insurance review department
IT	intrathecal
ITMP	intrathecal morphine pump
KNHI	Korean national health insurance
KRW	Korean Won
MA	medical aid
MEDD	morphine equivalent daily dosage
Mon	month
NRS	numerical rating scale
NY	New York
PTPS	posttraumatic pain syndrome
SNUH	Seoul National University Hospital
USA	United States of America
WCP	worker's compensation plans