ORIGINAL REPORT

Outcome of Continuous Intrathecal Opioid Therapy for Management of Chronic Pain in Iranian Veterans of the Imposed Iraq- Iran War

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Abstract- Among patients with chronic unrelieved pain, war veterans of eight years long Iraq - Iran war deserve especial attention. They not only suffer from severe intractable pain but also should bear some intangible consequences of unrelieved pain and severe disability. This perspective study reviews the outcome of implantation of intrathecal opioid pumps in these patients. Ten war veterans (mean age 43.36) with chronic nonmalignant pain included in this perspective study. Medical records reviewed to identify pain diagnosis, medication intake prior to implantation, details of the intrathecal opioid trial and date of implantation, surgical and technical complications. Outcome measures were global pain relief, physical activity levels, intrathecal opioid side effects, medication consumption and patient satisfaction. Overall pain relief at the time of study was 60%. Mean pain relief was 53%. A majority of patients reported improvements in physical activity levels and were satisfied with this type of therapy. Impotence and constipation were two most common pharmacological side effects. No surgical complication reported. The study showed that this type of therapy in Iranian war veterans improved analgesia, increased self-report physical activity levels and in spite of high incidence of pharmacological side effects, most of the patients were satisfied with this type of therapy. These results are comparable to those of previous studies in this field.

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Introduction

The first clinical use of an implantable intrathecal opioid pump was reported in 1981 in chronic pain of malignancy (1). Studies performed later supported its efficacy and safety and provided an alternative way for the management of chronic pain (2).

Chronic unrelieved pain is a major burden on health care resources worldwide. This economic strain on society comes through lost productivity and disability (3).

There is no data available on pain prevalence and its social and economic costs in Iran. No study, so far, has tackled the issue of chronic pain in Iran and its prevalence remains unclear especially in general population. Among patients with chronic unrelieved pain, war veterans of eight years long Iraq - Iran war deserve especial attention. They not only suffer from severe intractable pain but also should bear some intangible consequences of unrelieved pain and severe disability including depression, frustration and anger. This descriptive study reviews the outcome of implantation of intrathecal opioid pumps in these patients.

Materials and Methods

All patients implanted with intrathecal opioid pumps were identified through their monthly visit to pain clinic to have their pumps refilled. Their clinical records were reviewed to identify pain diagnosis, medication intake prior to implantation, details of the intrathecal opioid trial and date of implantation, surgical and technical complications. They were asked to take a questionnaire. Information requested included: pain treatments prior to

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pump implantation, technical and surgical complications of the procedure and pharmacological side effects of therapy.

Global pain relief was measured with an 11- point Likert scale (0 to 100 % relief since the time of commencement of intrathecal opioid) and change in activity levels with a five-point categorical scale (less active, no change, slightly more active, moderately more active, much more active). Satisfaction with the therapy was assessed on a six-point categorical scale (very dissatisfied, moderately dissatisfied, slightly dissatisfied, slightly satisfied, moderately dissatisfied, very dissatisfied). Patients who failed to respond to the questionnaire or were receiving intrathecal infusions of other drugs (baclofen) were excluded.

Results

From 1380 to 1388, intrathecal opiod pump were implanted in 13 patients in Khatam Ol Anbiya Hospital in Tehran. Two patients who were receiving intrathecal infusion of baclofen for spasticity excluded from study. Eleven patients had intrathecal opioid pump. One patient refused to take the questionnaire and was excluded too. Overall, 10 patients returned the questionnaire and participated in study. Mean age at the time of study was 43.36 years (range 41-53).

The implanted pumps were Medtronic Isomed, reservoir volume 35cc and a constant rate of infusion 1cc/24h. Buprenorphine was the agent used in the pumps. Prior to implantation of the pump and during treatment process, all patients had several psychological assessments. No data were available regarding intraspinal opioid trial and possible side effects and complications. Patients suffered chronic non-malignant pain due to injuries during the war and had received several different treatments. No change in pain intensity and improvement in the quality of life were documented following those treatments. Majority of patients (9 out of 10) suffered severe chronic pain in lower extremity.

Global pain relief

A majority of patients (6 out of 10) reported that, from the time of commencement of intrathecal opioids to the time of this study overall pain relief was 60% or greater. Four patients reported a pain relief of 0-40%. Mean pain relief was 53 % (Figure 1).

Physical activity and sleep

Patients reported the following impact of intrathecal opioid on their activity levels: less active two, no change two, slightly more active one, moderately more active three, much more active two. Majority of patients (6 out of 10) reported an increase in activity levels following intrathecal opioid therapy. Four patients reported either no change or a decrease in activity (Figure 2). Regarding the night sleep, four patients reported no change and the rest were satisfied with improvement in the quality of night sleep.

Medication consumption

Complete medication data were not available for patients. They reported taking a wide range of drugs from NSAIDS, methadone to mitrazapine. Since we could not find any documentation of prescriptive drugs in patient's medical records before and after pump implantation, we were unable to do any analysis such as Medication Quantification Score (MQS) at the time of our study.

Pharmacological side effects of intrathecal opioid

Patients asked to report any significant side effect that had occurred at any time since pump implantation. Patients could choose more than one answer.

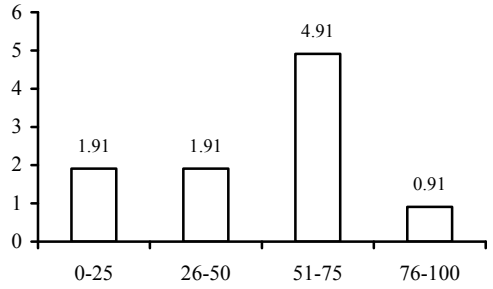

Figure 1. Global pain relief (%) in 10 patients with chronic nonmalignant pain treated with intrathecal opioid

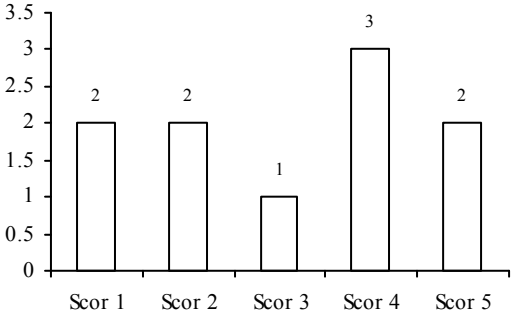

Figure 2. Distribution of physical activity scores in 10 patients

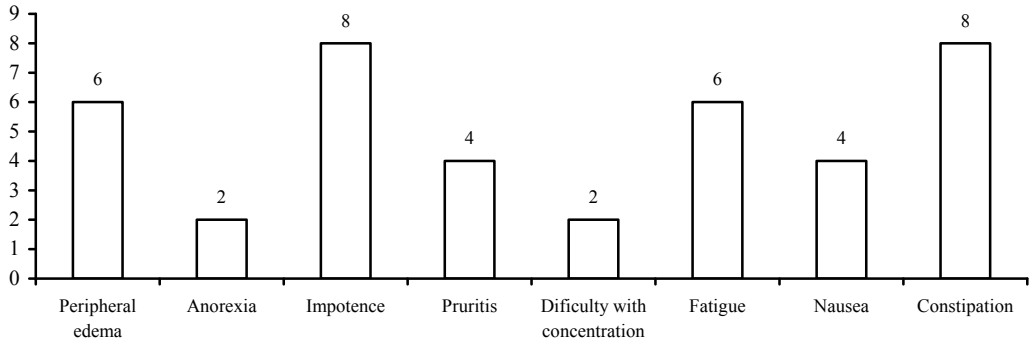

Figure 3. Pharmacological side effects of intrathecal opioids

Adverse effects reported in descending order of frequency were: impotence and constipation in eight, fatigue and peripheral edema in six, pruritis and nausea in four, difficulty with concentration and anorexia in two. Sexual dysfunction and constipation were two major side effects reported by the patients (Figure 3).

Surgical and mechanical complications

None of the patients developed any surgical complication such as bleeding, neurological injury, infection or headache due to pump implantation. Only one patient reported some mechanical complications such as catheter dislodgement and pump failure.

An interesting finding was the existence of Spinal Cord Stimulator (SCS) in two patients, which had not been removed before intrathecal pump implantation.

Satisfaction with therapy

A majority of patients (6 out of 10) expressed satisfaction with intrathecal opioid therapy. Four patients indicated that they were not satisfied with the therapy.

Discussion

In Iranian society, among patients with chronic non-cancer pain, war veterans deserve special attention. Due to war injuries these patients along with chronic pain, suffer from physical disability, dramatic change in life style, work status, social activities. Several studies have tried to assess the long-term clinical outcome of war related injuries in this particular group (4,5). As far as we know no study has tackled the issue of chronic pain , its effects on Iranian war veterans and the outcome of different therapies.

This descriptive study in this group of patients with chronic non-cancer pain who were under infusion of opioid via an implanted pump , was associated with reports of improved analgesia and night sleep . A majority reported improvements in physical activity following therapy. It seems that no study has demonstrated a significant change in work status because of intrathecal opioid therapy (6,7). we could not assess the positive effect of pain relief on work status of these patients since all of them had been integrated in an "employed status program" initiated by Janbazan foundation and were receiving monthly salaries as if they were fully employed. Indeed, it seems that in this group of patients who suffer from very severe non-cancer pain and high levels of disability and dysfunction, significant change in physical activity may be amore realistic outcome than returning to work.

The reported average pain relief of 53% is similar to other studies conducted on patients who were receiving intrathecal opioid therapy (6,8). We believe that interpretation of this average pain relief should be done in the context of pain severity and extent of disability in this particular group of patients and 53% average pain relief should be considered a significant outcome of the therapy.

Some studies reported that neuropathic pain syndromes have the best outcome with this type of therapy (8) and others found that the response is best in somatic pain syndromes (9-12). We did not have sufficient data to classify these patients's pain as predominantly neuropathic or nociceptive.the most common type of pain in our patients was lumbar spinal and lower extremity and most likely, the pain had a mixed nociceptive and neuropathic origin .reviewing medical records did not help us to clarify the origin of the pain.

In literature, Incidence of technical complications with the pump delivery system is up to 20% (13). In our study, only one patient reported to develop technical

complications with catheter and pump failure and there was no report of surgical complication. We noticed a high incidence of pharmacological side effects. Since we could not quantify medication consumption prior and after pump implantation due to incomplete documentation, interpreting or attributing these side effects to this type of therapy could be misleading. Some patients continued to take different medications on their own and were reluctant to disclose it.

Sexual dysfunction in patients suffering from chronic pain could be multi factorial. Majority of patients in our study complained of impotence and this is not comparable to the findings of other studies (13,14).

Our findings are limited by the retrospective nature of the study. Reliance on patient self-report without collaboration with objective measures of function may give false positive results. An alternative way could have been to seek spouse report of outcome in a different and carefully formatted questionnaire. In conclusion, during the past decade, intrathecal opioid therapy for intractable pain has evolved into a useful clinical treatment. Our findings indicate that this type of therapy in Iranian war veterans improved analgesia, increased self-report physical activity levels and in spite of high incidence of pharmacological side effects, most of the patients were satisfied with this type of therapy. These results are comparable to those of previous studies in this field.

Recommendations

There is no doubt that patients with intrathecal pumps require ongoing resources including prescription adjustments, refills, and most importantly monitoring of effectiveness. Therefore, enough attention should be paid to document properly all the parameters necessary in evaluating the effectiveness of this expensive modality of treatment and this will pave the way to conduct next studies with less limitations.

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