Dexamethasone in Preventing Post-Dural Puncture Headache: a randomized, double-blind, placebo-controlled trial

M. R. DOROUDIAN (*), M. NOROUZI (*), M. ESMAILIE (*) and R. TANHAIEVASH (**)

Abstract. Spinal anesthesia is major complication is Post-Dural Puncture Headache (PDPH) which is an intense and debilitating event. We decided to assess if intravenous administration of dexamethasone can decrease the incidence and/or intensity of this kind of headache. For this purpose 178 patients, who were supposed to undergo lower extremity orthopedic surgery, were enrolled in the study. Before spinal anesthesia was initiated, the first group (DMX-group) received 2 mL intravenous (IV) dexamethasone whereas the second group (PCB-group) received 2 mL IV normal saline. After termination of surgery, a 7 days follow-up started to observe the possible occurrence and intensity of PDPH. There was no statistically significant difference between DMX and PCB groups regarding the incidence of PDPH. However, the intensity of headache differed between the two groups being less severe if IV dexamethasone had been given prophylactically. Dexamethasone can be used to decrease the severity of PDPH in patients who receive spinal anesthesia.

Key words: Dexamethasone; Post-Dural Puncture Headache; Spinal anesthesia.

INTRODUCTION

Headache is the most troublesome complication of dural puncture which occurs in up to 30-60% of patients receiving spinal anesthesia (1, 2). This phenomenon is actually related to age, gender, needle size, pregnancy and a previous history of Post-Dural Puncture Headache (PDPH) (3, 4). Up to date there is still no approach which has demonstrated to offer complete prevention or treatment of PDPH. The currently proposed suggestion regarding prevention of PDPH consists of choosing the optimal needle size and tip in addition to the technique of insertion (5, 6). Pharmacologically little has been reported with respect to possible prevention of this complication. From a theoretical point of view, corticosteroids may have a place in preventing PDPH. Besides, dexamethasone is a frequently administered medication for treating headaches of various etiologies (7-9). Therefore, the purpose of the present study was to evaluate whether intravenous administration of dexamethasone might be useful as a prophylactic agent against the occurrence or severity of PDPH.

MATERIALS & METHODS

Study design

The present randomized, double-blind, placebo-controlled trial was performed in Shahid Bahonar Hospital, Kerman Medical University, Kerman, Iran after institutional board approval and informed consent from the patients was achieved.

The randomization process was performed using Random Allocation Software® (Version 1.0, May 2004) (10) by which patients were categorized into two groups either the treatment group or the placebo group.

Inclusion criteria

From 2007 through 2008, all ASA level of I-II (grade I-II in the classification of the American Society of Anesthesiologists) adults coming or being referred to our center for orthopedic center for lower extremity surgery were considered to enter the study protocol.

Exclusion criteria

Excluded are patients with a history of hypotension, Diabetes Mellitus, dexamethasone intolerance or past hypersensitivity reaction to it,
intake of any analgesic or anti-inflammatory agent
during the week prior to admission, past history of
chronic headache, recent onset acute headache,
contra-indication for lumbar puncture, a surgical
procedure estimated to last longer than 90 minutes,
current pregnancy, past /active peptic ulcer disease,
active systemic fungal infection, any kind of addiction,
more than two attempts for spinal anesthesia,
any history of cardiopulmonary disorders, long
term admission which does not permit patient to
resume the upright position within the first 7 days,
severe post-spinal hemodynamic changes (e.g.
severe hypotension or bradycardia) requiring exten-
sive fluid replacement therapy or resuscitation and
finally, strong dependency to tea or caffeine.

Treatment and placebo group

First of all, each patient received 500 mL
intravenous normal saline (sterile 0.9% sodium
chloride solution). Thereafter and before the initia-
tion of spinal anesthesia, all patients in the treat-
ment group received 8 mg (2 mL) dexamethasone
(DXM group) intravenously whereas in placebo
group (PCB group) 2 mL of normal saline was
administered intravenously. For all injections, the
anesthetic staff was blind with respect to the group
allocation whereas patients were also unaware
regarding the content of the study injectate. Spinal
anesthesia was performed by an expert using a 22G
Quincke needle. Standard monitoring (electrocar-
diography, finger pulse oxymetry and non-invasive
blood pressure measurement) was implemented
before the start of the anesthetic procedure and
thereafter at 8 minute intervals.

Afterwards, on the first, second and seventh
postoperative day, patients were enquired for possi-
ble occurrence of spinal anesthesia induced
headache. A telephone follow-up was considered if
the hospital stay was shorter than 7 days.

If a headache complaint was present, all
symptoms of the patient in addition to pattern and
severity of the headache was recorded. Subsequently the patient was ordered to take oral
analgesics, preserve bed rest and initiate fluid
therapy.

The intensity of the headache was assessed
according to a previously performed study being as
follows (11):

Class I: Patient suffers from a mild headache
while sitting or walking.

Class II: Patient suffers from a moderate to
severe headache while sitting or walking.

Class III: Patient suffers from a moderate to
severe headache even in supine position which
impedes his/her daily activities.

Statistical analysis

Using SPSS 13® t-test and Chi-square test
were used for statistical analysis. Statistical signifi-
cance was set at a p-value of less than 0.05.

RESULTS

Of all patients coming to our center, 178 patients were found to match the inclusion
criteria to be enrolled in the study. Half of them
(n = 89) were allocated to receive DXM while
another 89 patients (50%) were randomized to
become the PCB group. DXM group patients did
not differ from the PCG patients with respect to age
(mean 41.7, range 31-53 and 40, range 30-50 yrs
resp.). None of the patients left or had to leave the
study. Moreover, our population consisted of 117
(65.7%) men and 61 (34.3%) women. The DXM
and PCB groups consisted of 59 (66.3%) men and
30 (33.7%) women versus 58 (65.2%) men and 31
(34.8%) women, respectively.

Comparison between DXM and PCB regard-
ing age and sex has shown no significant different
which confirms the random distribution of subjects
(p = 0.075 and 0.325, respectively).

Furthermore, no significant difference was
detected between the two groups regarding the
occurrence of PDPH (p = 0.284). In the DXM
group 15 (16.8%) patients complained of headache
consistent with PDPH whereas in the PCB group it
was only slightly more i.e patients 19 (21.2%).

However, the severity of the headache was
significantly (p = 0.046) less in the DXM group as
opposed to those patients receiving placebo). In the
DXM group mostly class I headache was noticed
whereas Class II and Class III headaches were
registered more particularly in the PCB group
(Table 1).

Gender was shown to have no impact (p =
0.612) on the incidence of headache regardless of
the group allocation (Table 2) neither had the
number of attempts to enter the subarachnoid space
(p = 0.315) (Table 3).

DISCUSSION

Spinal anesthesia is one of the oldest modalities for providing pain relief in patients undergoing
Dexamethasone AND POSTDURAL PUNCTUREHEADACHE

Table 1

<table>
<thead>
<tr>
<th>Headache intensity</th>
<th>DXM n (%)</th>
<th>PCB n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>8 (53.3%)</td>
<td>5 (15.8%)</td>
</tr>
<tr>
<td>Class II</td>
<td>5 (33.3%)</td>
<td>8 (42.1%)</td>
</tr>
<tr>
<td>Class III</td>
<td>2 (13.3%)</td>
<td>8 (42.1%)</td>
</tr>
</tbody>
</table>

DXM: dexamethasone, PCB: placebo.

Table 2

<table>
<thead>
<tr>
<th>Headache</th>
<th>DXM n (%)</th>
<th>PCB n (%)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>+</td>
<td>5 (16.7%)</td>
<td>7 (22.6%)</td>
</tr>
<tr>
<td></td>
<td>–</td>
<td>25 (83.3%)</td>
<td>24 (77.4%)</td>
</tr>
<tr>
<td>Male</td>
<td>+</td>
<td>10 (16.9%)</td>
<td>12 (21.1%)</td>
</tr>
<tr>
<td></td>
<td>–</td>
<td>49 (83.1%)</td>
<td>45 (78.9%)</td>
</tr>
</tbody>
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DXM: dexamethasone, PCB: placebo.

The results of the present study indicate that intravenous (IV) administration of dexamethasone prior to spinal anesthesia cannot prevent the occurrence of PDPH but that such an approach may effectively limit the incidence of Class II and Class III headaches as especially the number of patients with Class III headache in PCB and DXM group decreased form 8 (42.1%) to 2 (13.3%), respectively. This may improve the quality of life during the postoperative period in patients suffering PDPH following spinal anesthesia.

In 2007, Noyan AShRAF et al. have demonstrated that IV hydrocortisone can significantly decrease the intensity of headache in women who underwent cesarean section under spinal anesthesia in the 48 hours following surgical delivery (15).

Similarly, in a case series of three women with vaginal delivery/cesarian section, IV cortisone caused a dramatic response to PDPH. In this study, Moral TUREIL et al. have suggested in 2002 that clinical trials are necessary to establish the role of steroids in treatment of PDPH (16). Three years later, in 2005, NEVES et al. in their case series of three patients have reported one woman with cesarian delivery who relieved completely (after conventional treatments of PDPH failed) and two cases of dural puncture who did not develop PDPH when IV hydrocortisone was administered prophylactically (17). Moreover, De Matteis et al. revealed that epidural administration of 1.5 mg diluted betamethasone may prevent PDPH effectively (18).

The preventive effect of corticosteroids against PDPH can be due to their anti-inflammatory effect on the inflammatory process initiated at puncture site. As these drugs suppress the synthesis of inflammatory mediators in immune cells, these will be released to a lesser extent into CSF and therefore, the number of stimulated pain receptors in CNS may decrease as well (15).

Of the 178 patients, only 15 needed a second dural puncture attempt which was found to have no significant impact on the incidence of PDPH. Moreover, the number of women suffering PDPH was less than might have been expected. This may be explained by the absence of pregnant women in our study population.
This is the first study in which the role of dexamethasone in preventing PDPH was assessed and according to the achieved results, we postulate that dexamethasone and possibly other corticosteroids as well can be used as a preventive medication to decrease the severity PDPH. Although the adverse effects of corticosteroids should not be ignored, single IV use of them seems to be safe enough to be considered as an alternative or additional option in the algorithm when faced with accidental or intended dural punctures, especially with conventional and/or too large bore needles.

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References