Original Article

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Dexamethasone Induced Perineal Pruritus in Patients Undergoing Minor Oral Surgical Procedures- A Prospective Cohort Study

Dentistry Section

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ABSTRACT

Introduction: Dexamethasone is frequently used by oral and maxillofacial surgeons to control postoperative oedema and pain in minor oral surgery procedures. Intravenous administration of dexamethasone may result in perineal pruritus i.e., perineal itching, pain and burning sensation. Different studies previously have reported these symptoms in patients. The incidence of these symptoms can vary between 25-100% depending on the dose of dexamethasone administered.

Aim: To evaluate the relationship between intravenous administration of dexamethasone and perineal pruritus in patients requiring minor oral surgical procedures; and its association with the phase of the menstrual cycle in female patients.

Materials and Methods: A prospective cohort study was conducted in the Department of Dentistry, Apollo Hospitals, Secunderabad, Telangana, India, which included 81 patients (43 females and 38 males) between October 2020 to March 2021. All patients included in the study were given preoperative 2 mL (8 mg) of intravenous dexamethasone, 30 minutes before commencing the minor oral surgical procedures and patients were enquired about symptoms of perineal pruritus. Female patients were asked about the phase of the menstrual cycle. All observations recorded were analysed using the Chi-square test and Spearman's analysis. Statistical Package for the Social Sciences (SPSS) version 26.0 software was used for statistical analysis and p-value <0.05 was considered statistically significant.

Results: A total of 81 patients (aged 19-52 years) were assessed, with the mean age of male patients being 29.3 years, and the mean age of female patients being 28.7 years. Most patients (female 82% and male 35%) experienced symptoms of itching and burning sensation for 60-90 seconds, which subsided without any further treatment. Female patients out numbered the male patients in experiencing the symptoms of perineal pruritus significantly (p-value <0.001). Correlation coefficient was 0.234 (p-value=0.037) which showed a weakly but positive correlation which was statistically significant between the phase of the menstrual cycle and symptoms experienced.

Conclusion: The study established a relation between the administration of i.v. dexamethasone and perineal pruritus. The symptoms were found to be more evident in females and the intensity of the symptoms varied with phases of the menstrual cycle. Females in the postovulatory phase and postmenopausal phase had experienced it more than others. Hence, the knowledge of such incidence and prior education of the patient would reduce the unpleasant experience.

Keywords: Anti-inflammatory agents, Endometrial cycle, Glucocorticoids, Ovarian cycle, Perineum

INTRODUCTION

Dexamethasone is a synthetic glucocorticosteroid with minimal mineralocorticoid activity, which has been in use since the 1960's to reduce inflammation in a range of conditions, including allergic reactions, autoimmune disorders, inflammatory disorders and certain types of cancers. In 1977, the World Health Organisation (WHO) listed it in the model list of essential medicines, as part of multiple formulations and thereafter to date it has been an off-patent product, which is also economically viable in most of the countries [1].

Dexamethasone has also been preferred and proposed by Oral and Maxillofacial Surgeons to control postoperative oedema and pain because of its formidable anti-inflammatory and analgesic properties [2]. It is commonly given perioperatively, either intramuscularly or intravenously. Intravenous administration of dexamethasone in third molar surgery has been extensively studied [3-7] and it has emerged that it bears no detrimental impact on wound healing, even with patients who are predicted to be at high risk for delayed clinical recovery [7].

It is frequently used as a single dose treatment to prevent postoperative swelling, pain, nausea and vomiting and when administered, did not have any significant long or short term adverse effects [8]. It is also worth mentioning that intravenous administration of dexamethasone may result in perineal pruritus i.e. perineal itching, pain and burning sensation. These symptoms have been reported by many patients in different studies [9-14].

Perineal pruritus incidence has been found to vary (25-100%), in studies conducted by different authors, depending on the dose of dexamethasone used [9,10,15-19]. Perineal Pruritus after intravenous dexamethasone is not uncommon [9,10,15-19] but has not been studied in the oral and maxillofacial speciality.

The current study was conducted to analyse and evaluate the association between intravenous administration of dexamethasone and perineal pruritus, in patients requiring minor oral surgical procedures, and to determine its correlation with menstrual cycle phase (preovulation, ovulation, postovulation and postmenopausal) in female patients.

MATERIALS AND METHODS

A prospective cohort study was conducted in the Department of Dentistry, Apollo Hospitals, Secunderabad, Telangana, India, from October 2020 to March 2021. Requisite, prior Ethical Clearance with number (AHS-ADS-001/10-20) was obtained to conduct the study and informed consent was taken from the patients for administering the drug. Total 81 patients (43 females and 38 males) were selected randomly irrespective of their caste, creed, religion or socio-economic status.

Sample size calculation: The sample size was calculated using G Power software (version 3.1.9.4). Based on the previous studies [20,21] the calculated effect size of 0.35 and keeping the standard values of alpha error at 0.05 and power of the study at 95%.

Fixing the confidence interval at 95% with 5% level of precision the minimum sample size of the study was 79.

Inclusion criteria: Patients with American Society of Anaesthesiology (ASA) I classification [22] and no history of steroid or analgesics intake were included in the study.

Exclusion criteria: Patients of ASA II,III,IV and with history of steroid or analgesics intake were excluded from the study.

Study Procedure

Local anaesthesia administered was 2% lignocaine with 1:80,000 adrenaline used as nerve block and infiltration. All patients considered in the study were given preoperative 2 mL (8 mg) of intravenous dexamethasone, 30 minutes [23] before commencing the minor oral surgical procedures like extraction of difficult and impacted teeth, apicoectomy. The advantage of administering the medicine prior to surgery ensures better drug absorption and the therapeutic blood level shall be achieved well before the inflammation begins [24].

Injection dexamethasone (brand name injection dexasone) manufactured by Cadila Pharmaceuticals containing 4 mg of dexamethasone phosphate in 1 mL of the solution with preservative sodium methylparaben (5% w/v) and sodium propylparaben (0.02% w/v) was used. All patients received an undiluted intravenous dose of 2 mL (8 mg) preoperatively. They were injected intravenously in an antecubital vein using a 25 gauge needle attached to 2 mL Leur-lock syringes (unolok 2 mL syringes by Hindustan Syringes and Medical Device).

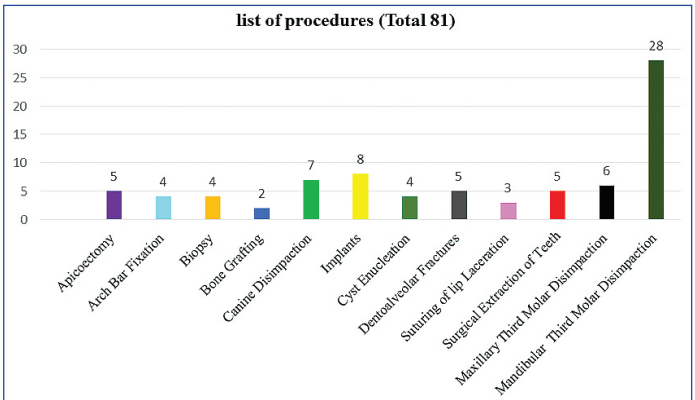
Patients were elucidated about the side-effects of perineal pruritus and were asked to report any itching or burning sensation and pain in the perineal area during and post the injection. A 7-point Likert scale was used for assessment and grading of pain. Female patients were specifically enquired, about their menstrual cycle, duration of their being in their preovulation, present and postovulation phase to establish any relation of their symptoms with the phase of their menstrual cycle.

STATISTICAL ANALYSIS

Observations were recorded and were analysed by a statistician using Statistical Package for the Social Sciences (SPSS) version 20.0 software. A Chi-square test was used to show the gender-wise distribution of study subjects for perineal pruritus. Spearman's correlation was analysed between the stages of the menstrual cycle and perineal pruritus among female patients in the study. The p-value <0.05 was considered statistically significant.

RESULTS

The present study was conducted on 81 patients who had undergone minor surgical procedures under local anaesthesia as depicted in [Table/Fig-1]. The age of the patients ranged from 19-52 years. The mean age of male patients was 29.3±8.05 years and that of female patients was 28.7±6.25 years.



[Table/Fig-1]: List of minor surgical procedures carried out from October 2020 to March 2021.

Most patients experienced symptoms of itching and burning sensation in the perineum (n=48) 60% for 60-90 seconds which subsided, without any further treatment. One patient could not define the feeling experienced and was not included for the analysis part of the study. The pain was felt by only three patients which subsided after a while and was scored 4 (moderate) on Likert scale. In the present study, most female subjects showed the presence of perineal pruritus (82%, n=32) as compared to the males (35%, n=13). This difference was seen to be statistically highly significant p-value <0.001 [Table/Fig-2].

Gender	Perineal pruritus		Total	p-value
	Present (n, %)	Absent (n, %)		
Male	13 (35)	24 (65)	37	<0.001*
Female	35 (82)	8 (18)	43	
Total	48 (60)	32 (40)	80	

[Table/Fig-2]: Chi-square test showing the gender wise distribution of study subjects for perineal pruritus.
*p-value <0.05 is considered statistically significant

A 25.58% of female patients were in preovulation phase of their menstrual cycle. A 27.9% of the females were in the postovulatory phase. A 34.88% of them were in postmenopause phase [Table/Fig-3].

Menstrual phase	Frequency (n, %)	Symptoms present (n, %)
Preovulation	11 (25.58)	9 (23.68)
Ovulation	5 (11.62)	5 (13.15)
Postovulation	12 (27.90)	11 (28.94)
Postmenopausal	15 (34.88)	13 (34.21)
Total	43 (100)	38 (100)

[Table/Fig-3]: Frequency distribution of the female study participants depending on the stages of ovulation.

There was a statistically significant but weakly positive Spearman's correlation between the phase of the menstrual cycle and perineal pruritus symptoms experienced (r=0.234, p-value=0.037).

DISCUSSION

Inflammation and oedema are limited by the preoperative administration of corticosteroids. This is in agreement with a study conducted by Bamgbose BO et al., and Antunes AA et al., who concluded that dexamethasone is the preventive strategy for limiting postoperative oedema and trismus following third molar extractions [25,26]. Moore PA et al., also reiterated the efficacy of pre-emptive NSAIDs and corticosteroids in avoiding a variety of postoperative complications [27]. Postoperative swelling and oedema may be partly due to the conversion of phospholipids to arachidonic acid by phospholipase A2, and the resultant production of leukotrienes, prostacyclins, prostaglandins and thromboxane A2 which act as mediators of the inflammatory response. The use of steroids may act to inhibit the initial step in this process [23].

They act by inhibiting vascular dilation produced by histamine and reducing the transudation of fluids, thus the formation of oedema. They hinder deposition of fibrin around the inflamed area and inhibit leukocyte chemotaxis, phagocytosis, Kinin generation and arachidonic acid formation, thereby suppressing the surge for the formation of prostaglandins and cyclooxygenase end products. All phases of inflammation are blocked which accounts for the anti-inflammatory potency of steroids resulting in a significant reduction in oedema and swelling [28].

Corticosteroids have been used effectively as an adjunct to analgesics in oral and maxillofacial surgery to reduce postoperative oedema and pain [24]. Corticosteroids that can be used in oral surgical procedures include long-acting drugs like dexamethasone, betamethasone, intermediate duration like prednisone, prednisolone, methylprednisolone, and triamcinolone, short-acting drugs hydrocortisone [29].

Dexamethasone is universally preferred among these for minor oral surgical procedures. It is one of the most active glucocorticoids, being about 25-30 times as potent as hydrocortisone. Absorption of dexamethasone is rapid following intravenous injection. The biological half-life of dexamethasone is about 190 minutes and small amounts of dexamethasone are bound to plasma protein. It is metabolised primarily in the liver and inactive metabolites are excreted in the urine, mainly as glucuronides and sulphates, and also as unconjugated metabolites. Small amounts of unchanged drugs are also excreted in the urine. Up to 10-65% of a dose of dexamethasone is excreted in the urine within 24 hours [30].

The potential advantage of dexamethasone is that of its low cost and long clinical effect, lasting 24-36 hours [31]. To achieve the desired anti-inflammatory effects, corticosteroids must be administered in doses exceeding the normal physiologic amounts released by the body [32] and should preferably be given before the infliction of tissue damage and not during or after surgery to achieve better control on postoperative pain [33,34] in addition to less nausea and vomiting.

A preoperative dose of 8 mg given intravenously has been recommended by many authors [33-35] and our study also has followed the same protocol. Al-Shamiri HM et al., in their study found that preoperative oral administration of 8 mg dexamethasone was more effective in reducing oedema following third molar surgery compared to postoperative administration of the same dose [4].

Intravenous route i.v. route administration was preferred as preoperative intravenous dexamethasone facilitates recovery reducing pain and postoperative nausea and vomiting [36]. Intravenous dexamethasone does not seem to cause any significant long or short-term adverse effects, but the unfavourable effect of transient excruciating perineal itch and pain has been documented previously[17]. In the present study, patients experienced burning sensation and itching in the perineal region for a short period (60-90 seconds) which subsided without any intervention. This is in agreement with a study conducted by Perron G et al., who observed short-lived perineal itching and burning sensation postadministration of i.v. dexamethasone [13].

Neff SP et al., have stated that pain appears to be short-lived and pain may be reduced by either dilution and slow drugadministration (e.g., 8 mg dexamethasone diluted in 50 mL of 0.9% sodium chloride, infused over 1 minute) [10,27,28]. Analogous conclusions were witnessed by Singh M et al., where they stated that 43% of patients were having perineal pruritus after receiving 0.15 mg/kg dexamethasone via a peripheral line [9]. They concluded that dexamethasone used for prophylaxis and treatment of postoperative nausea pain vomiting may cause perineal pruritus/pain of variable intensity in awake patients.

There is no established hypothesis to explain these adverse effects, but it is speculated that corticosteroid phosphate esters such as the dexamethasone sodium phosphate, as used in the present study cases, are the cause of the perineal pain and irritation. Perineal irritation has been described with hydrocortisone-21 phosphate sodium and prednisolone phosphate. Incidence and severity of burning sensation and itching are directly proportional to the concentration of organic phosphate in the blood [10,16].

Itch pathway and itch sensation are received by the unspecialised free nerve endings located close to the dermo-epidermal junction and is transmitted by polymodal, unmyelinated C fibres entering the spinal cord and thalamus. The important pharmacological mediators of itch sensation include histamine, acetylcholine, substance P, Calcitonin Gene-Related Peptide (CGRP), opioid peptides, proteases, bradykinin, serotonin, platelet-activating factor, neurotrophins, prostaglandin E and cytokines [37].

Wang J et al., have proposed that dexamethasone may participate in the pathogenesis of pruritus through activated sodium channels in peripheral unmyelinated C fibre polymodal afferents within superficial layers of skin and mucous membrane [14].

The short duration of pain and pruritus (60-90 seconds) observed in our study might be attributed to the time required for the compound to be hydrolysed to phosphate ions and dexamethasone [38]. Repeated administrations could cause similar effects, suggesting this as a potential aetiology. However, the path physiology of this rare side effect remains a conundrum and further research is required.

Singh M et al., observed that incidence of perineal pruritus was more in female patients and it was statistically significant (p-value <0.05) [9]. Rewari V et al., conducted a prospective, randomised, double blind placebo controlled study on use of fentanyl pretreatment for alleviation of perineal symptoms following preoperative administration of intravenous dexamethasone sodium phosphate and had similar observations [39]. In the present study, both female and male patients were observed to report the symptoms, but females outnumbered male patients.

In a study by Perron G et al., among the twenty patients included in the study all the ten females (100%) experienced the symptoms while only three males were affected and Gu CY et al., observed that females had a higher incidence of dexamethasone-induced perineal pruritus (p-value <0.05) [13,40]. Their results are also similar to the present study where the incidence of perineal pruritus was more in female patients (p-value <0.001). They had also concluded in their study that females had a higher incidence of dexamethasone-induced perineal pruritus.

Authors of the present study further tried to find out the correlation between the appearances of pruritus and the menstrual phase in female patients and observed a weakly positive yet significant relationship. (Spearman's coefficient value=0.234 with p-value=0.037). It has been noted that females in the postovulatory phase and postmenopausal phase were affected more with these symptoms. Similar findings have been mentioned by Swamiappan M in their study [37]. This could be attributed to decreased oestrogen levels after ovulation and menopause as a cause for vaginal dryness [41]. Other authors speculated that the threshold levels of released neurotransmitters were lower in females [40]. The current study did not test the level of neurotransmitters.

It has been recommended that i.v. dexamethasone should be diluted in 50 mL saline and must be administered over 5-10 minutes to reduce the intensity of symptoms [13]. It has been proposed that dilution and prolonged injection time might have resulted in a slower release of neurotransmitters and not reaching the threshold levels, which ultimately helped to reduce the symptoms [40].

Limitation(s)

A larger sample size should be included to establish more accurate, substantial and statistical analysis of result on the correlation of the symptoms of perineal itching and pain with the menstrual cycle. Changes in the menstrual flow were not included in this study.

CONCLUSION(S)

Dexamethasone induced perineal irritation is a distinctive phenomenon that could be appalling to patients without them being cognizant of the real reason behind it. The study concludes that females are more prone to it vis-a-vis male. It transpires that females in postovulatory and postmenopausal phase experienced symptoms of perineal pruritus more than the other phases of menstrual cycle. However, this aspect needs further deliberation with research work done with a larger spectrum of patients. It is important to be acquainted with these symptoms and necessary precaution to be taken for preventing or minimising the suffering of patients.

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