

Comparison of the efficacy of ibuprofen and *Belladonna* in the control of orthodontic separator pain

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Abstract

Background: The purpose of this study was to compare the efficacy of ibuprofen and *Belladonna* in the control of orthodontic pain and to ascertain the pain relief by *Belladonna* in comparison with ibuprofen during orthodontic separation. **Materials and Methods:** Patients, between 20 and 35 years of age, 51 females and 21 males, were included in this study. Patients were randomly divided into two groups; one group was assigned to ibuprofen 400 mg and second group was allocated to *Belladonna* 6C group. Patients were given two doses of medication of their respective groups, 1 h before placement of elastomeric separators (Ormco Separators, Ormco Corporation, CA, USA) which was administered in the department and one dose 6 h after the placement. Pain scores recorded on visual analogue scale (VAS). VAS was a 10 cm scale with millimetre calibration to record their pain at the following intervals, 2 h after placement, 6 h after placement, bedtime, day 1 morning, day 2 morning, day 3 morning and day 5 morning. **Results:** *Post hoc* comparisons indicated that there was no difference between the two groups at 2 h ($P = 0.77$), 6 h ($P = 0.073$), 1 day ($P = 0.120$), 2 days ($P = 0.283$), 3 days ($P = 0.363$), 5 days ($P = 0.622$) and 7 days. **Conclusion:** Ibuprofen and *Belladonna* 6C are effective and provide adequate analgesia with no statistically significant difference. Lack of adverse effects with *Belladonna* 6C makes it an effective and viable alternative.

Keywords: *Belladonna*, Homoeopathy, Orthodontic pain, Separator

INTRODUCTION

Orthodontics is a specialised branch of clinical dentistry which uses the force/s as a tool for correction of various dentofacial malocclusion and deformities. Contemporary to medical sciences force/forces acts as a drug in orthodontia which are desired to bring out various dentofacial improvement; however, very frequently such force or force systems lead to pain/discomfort to the patients which may render a negative attitude towards the orthodontic care. The present widely recognised and accepted analgesics such as non-steroidal anti-inflammatory drugs (NSAIDs) have been proved to be effective and efficient in control of such unpleasant experience during orthodontic treatment; however, these preparations have an anti-inflammatory effect, which is extremely undesirable factor as it prevents orthodontic tooth movement by suppressing the inflammatory reactions which is very much desired for orthodontic tooth movement. Dr. Samuel Hahnemann in the year 1796 created a system of alternative

medicine based on his doctrine of *Similia similibus curentur* which means *Like cures Like*.^[1] Homoeopathy is debated field for many years. The results of Homoeopathy are not due to placebo-like effect which is contrary to the main stream thinking.^[2] Homoeopathic practice still continues to exist in many parts of the world and is believed to be specifically efficient and effective in curing chronic diseases which have only symptomatic treatment in the modern system of medicine. A deeper insight into homoeopathic literature brings into light on various analgesic preparations, for example, *Belladonna* and *Arnica* amongst which *Belladonna* is preferred medication in cases of acute pain.^[3,4]

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Tooth movement in orthodontics begins with insertion of elastomeric separators which are used to create the space for placement of band material around the tooth for attachment of bracket and auxiliaries are known to cause discomfort and pain to the patient in its initial days. Pain after separator placement increases gradually from the 4th hour to the 24th hour, but it subsides around the 7th day.^[5] An effective control of pain can have a huge impact on the perception of orthodontic care on the patient's mind and can significantly minimise the apprehension towards the treatment and in still a positive mental attitude towards the treatment.

NSAIDs have stood the test of time when it comes to pain management; however, they also come with an inherent property of being anti-inflammatory, thus basically acting against the theory of tooth movement. Paracetamol has a central site of action by inhibiting COX-3 centrally, thus not interfering with tooth movement, but it has been found that the efficacy of paracetamol is less than that of ibuprofen, which is peripherally acting non-selective COX inhibitor. It has been debated that single dose of NSAIDs is not sufficient enough to prevent tooth movement; however, the possibility still exists and the doors to search for alternatives remain wide open while considering ibuprofen as an established standard.

The purpose of the present study was to compare the efficacy of ibuprofen and *Belladonna* in the control of orthodontic pain and to ascertain the pain relief by *Belladonna* in comparison with ibuprofen during orthodontic separation.

MATERIALS AND METHODS

The study's experimental design and protocol were approved by the Ethical Committee of the ACPM Dental College, Dhule, Maharashtra, India. This study was conducted in Department of Orthodontics and Dentofacial Orthopedics of ACPM Dental College, Dhule, Maharashtra, India. Eighty patients, between 20 and 35 years of age, 51 females and 21 males, scheduled to undergo fixed appliance treatment, agreed to participate in the study. Patients were explained about the study, and informed consent was obtained from the patients. Cases with non-extraction treatment plan having proper contacts' mesial and distal to permanent first molar and currently not taking any analgesics or antibiotics were included in the study. Patients consuming analgesics or anti-inflammatory drugs or having a history of bronchial asthma, any history of hepatic or renal diseases, peptic ulceration or allergy to ibuprofen were excluded from the study.

Patients were randomly divided into two groups; one group was assigned to ibuprofen 400 mg and second group was allocated to *Belladonna* 6C group. In the *Belladonna* 6C group, four globules given to patient. Patients were given two doses of medication of their respective groups, 1 h before placement of elastomeric separators (Ormco Separators, Ormco Corporation, CA, USA) which was administered in the department and one dose 6 h after the placement.

A set of seven printed pages of visual analogue scale (VAS) along with instruction of how to record pain response (including local language) was given to patients. VAS was a 10 cm scale with millimetre calibration to record their pain at the following intervals: 2 h after placement, 6 h after placement, bedtime at 9 pm, day 1 morning, day 2 morning, day 3 morning and day 5 morning. Patients were asked to mark the appropriate response they felt on chewing and biting. Patients were instructed to call the attending doctor if he/she felt the pain unbearable so that necessary analgesic treatment can be administered to the patient.

Statistical analysis

Data were analysed using SPSS Inc. Released 2007. SPSS for Windows, Version 16.0. Chicago, SPSS Inc. Findings were summarised with the use of frequencies and percentages for categorical variables and means and standard deviations (SD) for continuous variables. Chi-square tests were used to compare proportion, and unpaired *t*-tests were used to compare the mean of continuous data in two groups. The null hypothesis presumed that there was no significant difference of the pain score at different time intervals which was the basis of analysis in between the two groups. Repeated measure ANOVA and simple effects tests were used to estimate VAS pain difference according to time and group. *P* values reported were two tailed and were considered significant at the 0.05 level.

RESULTS

In eighty patients, 51 (63.8%) females and 29 boys (36.3%) were included in the study. In ibuprofen group, 67.5% were female patients, and in *Belladonna* group, 60% were females. Mean age of patients in ibuprofen group was 21.8 (3, SD) years and in *Belladonna* group was 21.9 (3.2, SD) years [Table 1]. There was statistically no significant difference in the sex ($P = 0.485$) and age ($P = 0.914$) of patients included in either of two groups [Table 2].

Post hoc comparisons indicated that that there was no difference between the two groups at 2 h ($P = 0.77$), 6 h (0.073), 1 day ($P = 0.120$), 2 days ($P = 0.283$), 3 days ($P = 0.363$), 5 days ($P = 0.622$) and 7 days though the VAS pain was higher in *Belladonna* group than ibuprofen group [Table 3]. Mean VAS pain score at different time intervals after separator placement in ibuprofen and *Belladonna* group is given in [Figure 1].

There was a statistically significant effect of time on VAS pain score ($F = 1383.1$, $P < 0.001$), but there was no significant interaction between time and group ($F = 1.02$, $P > 0.05$). Indicating that there was no significant ($P > 0.05$) difference of pain score between the groups' different time intervals. Between subject, there was statistically no significant ($F = 140$, $P > 0.05$) difference of VAS pain in between the groups [Table 4].

DISCUSSION

Pain experienced during orthodontic treatment is not trifling and needs to be taken care of from the first

appointment with the orthodontist. Although a wide range of patient responses are present, pain and discomfort are generally experienced, which may instil a negative approach towards the treatment, or in very few cases may lead to discontinuation.^[6]

Minor et al.^[7] found that preemptive administration of ibuprofen significantly reduces pain scores as compared to post-separator placement and placebo group, also the peak plasma level concentration of ibuprofen in blood reaches in

1 h;^[8] hence, administration of ibuprofen 1 h before placement of separators was decided for the study.

Previous studies that have been conducted to compare the efficacy of various NSAIDs showed that ibuprofen 400 mg is consistent in reducing the pain scores when compared to placebo groups;^[5,6] however, *Naproxen sodium* has proved to be better than ibuprofen and placebo groups,^[5] whereas another study suggested that *Naproxen sodium* and paracetamol were at par to placebo groups. These previous studies show that conventional analgesics typically accepted by modern medicine may also fail to achieve the desired level of analgesia. However, ibuprofen had consistently proved its efficacy and also in the performed study. Gastric irritation is a common side effect possible with consumption of NSAIDs such as ibuprofen, although single dose administration clinically does not produce the aforementioned symptom; however, the potential of side effect still cannot be ruled out. Homoeopathic medications have no proven side effect.

The results of the present study indicated that peak pain levels were maximum after 24 h of placement and the average scores during the first 24 h of placement indicated that ibuprofen group was more effective than *Belladonna* 6C but here was no significant statistical difference present between the two groups in the first 24 h. Pain scores decreased after 24 h and but *Belladonna* 6C group scores were lesser than that of ibuprofen, which might be attributed to half-life of ibuprofen which is 1.8–2 h and the drug is completely eliminated from the system in 24 h.^[9,10] After 24 h, average *Belladonna* 6C pain scores are lower than ibuprofen group.

Table 1: Comparison of difference sex of patients in ibuprofen and *Belladonna* group

Sex	Group		Total (%)
	Ibuprofen (%)	<i>Belladonna</i> (%)	
Female	27 (67.5)	24 (60.0)	51 (63.8)
Male	13 (32.5)	16 (40.0)	29 (36.3)
Total	40 (100.0)	40 (100.0)	80 (100.0)

Chi-square tests

χ^2	df	P
0.487	1	0.485

Table 2: Comparison of mean age in ibuprofen and *Belladonna* group

Age (years)	Unpaired t-test	
	Ibuprofen (n=40)	<i>Belladonna</i> (n=40)
Mean	21.80	21.88
SD	3.00	3.22
Mean difference		-0.08
t		-0.108
P		0.914

SD: Standard deviation

Table 3: Repeated measure ANOVA

Time point	VAS pain, mean (SD)			P
	Ibuprofen (n=40)	<i>Belladonna</i> (n=40)	Mean difference (95% CI)	
2 h	45.75 (7.1)	46.25 (8.1)	-0.5 (-3.89-2.89)	0.77
6 h	55.50 (5.5)	58.25 (7.8)	-2.75 (-5.76-0.26)	0.073
1 day	38.50 (6.2)	40.75 (6.6)	-2.25 (-5.1-0.60)	0.120
2 days	30.25 (1.6)	31.25 (5.6)	-1 (-2.84-0.82)	0.283
3 days	21.50 (5.3)	22.50 (4.4)	-1 (-3.17-1.17)	0.363
5 days	3.00 (4.6)	2.50 (4.4)	0.5 (-1.15-2.51)	0.622
7 days	0.00	0.00	0.00	-

VAS: Visual analogue scale; CI: Confidence interval; SD: Standard deviation

Table 4: Repeated measure ANOVA: Univariate tests

	Source	Type III sum of squares	df	Mean square	F	Significant
Within-subjects effects	Time	220,596.786	6	36,766.131	1383.1	0.000
	Time × group	162.500	6	27.083	1.02	0.412
Between-subjects effects	Group	140.000	1	140.000	3.021	0.086

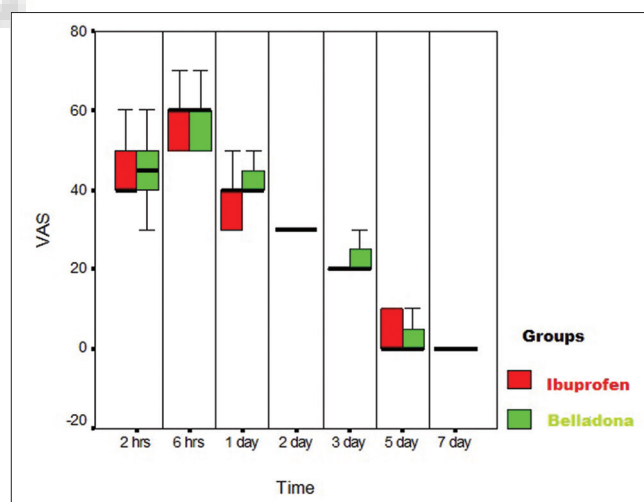


Figure 1: Mean visual analogue scale pain score at different time intervals after separator placement in Ibuprofen and *Belladonna* group

CONCLUSIONS

- Ibuprofen and *Belladonna* 6C are effective and provide adequate analgesia with no statistically significant difference
- Lack of adverse effects with *Belladonna* 6C makes it an effective and viable alternative.

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Conflicts of interest

None declared.

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ऑर्थोडॉंटिक विभाजक दर्द के नियंत्रण में इबुप्रोफेन और बैलाडोना की प्रभावकारिता की तुलना

सार

पृष्ठभूमि: इस अध्ययन का उद्देश्य ऑर्थोडॉंटिक दर्द के नियंत्रण में इबुप्रोफेन और बैलाडोना की प्रभावकारिता की तुलना करना था और ऑर्थोडॉंटिक अलगाव के दौरान इबुप्रोफेन की तुलना में बैलाडोना द्वारा दर्द निवारण का पता लगाना था।

विधि: इस अध्ययन में 20 से 35 वर्ष आयु के बीच के रोगी शामिल थे जिनमें 51 स्त्रियां और 21 पुरुष थे। रोगियों को यादृच्छिक तरीके से दो समूहों में विभाजित किया गया। एक समूह को इबुप्रोफेन 400 एमजी के लिए सौंपा गया और दूसरा समूह बैलाडोना 6सी को आबंटित किया गया। रोगियों को अपने संबंधित समूहों की दवा की दो खुराकें इलास्टोमेरिक विभाजक (ऑम्कोसपरेटर, ओर्मको कार्पोरेशन, सीए) लगाने के एक घंटे पहले दी गईं जो कि विभाग में लगाई गईं और एक खुराक विभाजक लगाने के 6 घंटे बाद दी गईं। वीएएस स्केल पर पीड़ा का स्कोर दर्ज किया गया। वीएएस मिलीमीटर कैलिब्रेशन के साथ 10 से.मी. का स्केल था जो निम्नलिखित अंतरालों: लगाने के 2 घंटे बाद, लगाने के 6 घंटे बाद, सोने के समय, पहले दिन सुबह, दूसरे दिन सुबह, तीसरे दिन सुबह और पांचवे दिन सुबह उनका दर्द दर्ज करने के लिए किया गया।

परिणाम: इस तुलना में संकेत पाया गया कि दोनों समूहों के बीच 2 घंटे (पी= 0.77), 6 घंटे (पी= 0.073), पहले दिन (पी=0.120), दूसरे दिन (पी=0.283), तीसरे दिन (पी=0.363), पांचवे दिन (पी=0.622), और सातवें दिन पर कोई अंतर नहीं है।

निष्कर्ष: इबुप्रोफेन और बैलाडोना 6सी प्रभावी हैं और किसी सांख्यिकिय महत्वपूर्ण अंतर के बिना पर्याप्त दर्दनाशकता प्रदान करते हैं। बैलाडोना 6सी के साथ प्रतिकूल प्रभाव का अभाव इसे एक प्रभावी और व्यवहार्य विकल्प बनाता है।

Vergleich der Wirksamkeit von Ibuprofen und Belladonna bei der Kontrolle von orthodontischen Separator Schmerzen

Abstrakt-

Hintergrund - Der Zweck dieser Studie war es, die Wirksamkeit von Ibuprofen und Belladonna bei der Kontrolle von kieferorthopädischen Schmerzen zu vergleichen und die Schmerzlinderung durch Belladonna im Vergleich zu Ibuprofen während der kieferorthopädischen Trennung zu ermitteln.

Methoden - Achtzig Patienten zwischen 20 und 35 Jahren, 51 Frauen und 21 Männer wurden in diese Studie eingeschlossen. Die Patienten wurden nach dem Zufallsprinzip in zwei Gruppen eingeteilt, wobei eine Gruppe 400 mg Ibuprofen und die zweite Gruppe der Gruppe Belladonna 6C zugewiesen wurde. Elastomere Separatoren (Ormco Separators, Ormco Corporation, CA) wurden in der Abteilung verabreicht. Die Patienten erhielten zwei Dosen der Medikamente ihrer jeweiligen Gruppen eine Stunde vor der Platzierung und eine Dosis 6 Stunden nach der Platzierung. Schmerzbewertungen wurden auf der VAS-Skala aufgezeichnet. VAS war eine 10 cm-Skala mit mm-Kalibrierung, um ihre Schmerzen in folgenden Intervallen, 2 Stunden nach der Platzierung, 6 Stunden nach der Platzierung, Bettzeit, Tag 1 Morgen, Tag 2 Morgen, Tag 3 Morgen und Tag 5 Morgen zu erfassen.

Ergebnisse - Post hoc-Vergleiche zeigten, dass es keinen Unterschied zwischen den zwei Gruppen gab bei 2 Stunden ($p = 0,77$), 6 Stunden ($0,073$), 1 Tag ($p = 0,120$), 2 Tage ($p = 0,283$), 3 Tage ($p = 0,363$), 5 Tage ($p = 0,622$) und 7 Tage.

Fazit- Ibuprofen und Belladonna 6C sind wirksam und bieten eine angemessene Analgesie ohne statistisch signifikanten Unterschied. Das Fehlen von Nebenwirkungen mit Belladonna 6C macht es zu einer effektiven und praktikablen Alternative.

Comparación de la eficacia de ibuprofeno y *Belladonna* en el control del dolor ocasionado por separadores ortodónticos

Resumen-

Fundamento- El objetivo de este estudio fue comparar la eficacia de ibuprofeno y *Belladonna* en el control del dolor ortodóntico y determinar el alivio del dolor con *Belladonna* comparación con ibuprofeno durante la separación ortodóntica.

Métodos- En este estudio, se incluyeron pacientes, 51 mujeres y 21 varones, con edades entre los 20 y 35 años. Los pacientes se dividieron aleatoriamente en dos grupos, un grupo fue asignado a 400 mg de ibuprofeno y un segundo grupo a *Belladonna* 6C. Los pacientes recibieron dos dosis de la medicación en los respectivos grupos, una dosis administrada en la consulta una hora antes de la colocación de los separadores elastoméricos (Ormco Separators, Ormco Corporation, CA) y una dosis 6 horas tras la colocación. Las puntuaciones del dolor se registraron en la escala VAS (escala de 10 cm con un calibrado en mm) para determinar el dolor en los siguientes intervalos: 2 y 6 horas tras la colocación, en el momento de ir a dormir, día 1 mañana, día 2 mañana, día 3 mañana y día 5 mañana.

Resultados- Las comparaciones post hoc indicaron que no hubo diferencias entre los dos grupos a las 2 horas ($p=0,77$) y 6 horas ($0,073$), así como en el día 1 ($p=0,120$), día 2 ($p=0,283$), día 3 ($p=0,363$), día 5 ($p=0,622$) y día 7.

Conclusiones- Ibuprofeno y *Belladonna* 6C son eficaces y proporcionan una analgesia adecuada sin diferencias estadísticamente significativas. Debido a la falta de efectos adversos, *Belladonna* 6C constituye una alternativa eficaz y viable.

Comparaison de l'efficacité de l'Ibuprofène et de la Belladonna pour contrôler la douleur provoquée par le séparateur orthodontique

Résumé:

Contexte: Le but de cette étude est de comparer l'efficacité de l'Ibuprofène et de la Belladonna pour contrôler la douleur dentaire et de vérifier le soulagement de la douleur apporté par la Belladonna par rapport à l'Ibuprofène durant la séparation orthodontique.

Méthodes: Quatre-vingts patients âgés de 20 à 35 ans, 51 femmes et 21 hommes, ont participé à cette étude. Ils ont été divisés au hasard en deux groupes, un groupe pour l'ibuprofène 400 mg et le deuxième groupe pour la Belladonna 6C. Les patients ont reçu deux doses du médicament de leur groupe dans la faculté une heure avant la pose des séparateurs élastomères (Ormco Separators, Ormco Corporation, CA) et une dose 6 heures après la pose. L'intensité de la douleur a été enregistrée sur une échelle VAS. La VAS était une échelle de 10 cm avec une calibration en mm pour enregistrer leur douleur aux intervalles suivants : 2 heures après la pose, 6 heures après la pose, au coucher, le matin du jour 1, le matin du jour 2, le matin du jour 3 et le matin du jour 5.

Résultats: Les comparaisons faites suite aux tests ont indiqué qu'il n'y avait pas de différence entre les deux groupes à 2h ($p=0,77$), à 6h ($0,073$), le jour 1 ($p=0,120$), le jour 2 ($p=0,283$), le jour 3 ($p=0,363$), le jour 5 ($p=0,622$) et le jour 7.

Conclusion: L'Ibuprofène et la Belladonna 6C sont efficaces et assurent une analgésie suffisante sans différence statistiquement notable. La belladonna 6C ne présentant pas d'effets indésirables, elle est donc une option efficace et viable.

比較布洛芬和顛茄在控制置入分牙圈的齒顎矯正疼痛的功效。

摘要

背景—本研究的目的是比較布洛芬和顛茄在控制置入分牙圈的齒顎矯正疼痛的功效，通過與布洛芬比較，確定顛茄在置入分牙圈期間舒緩疼痛的效果。

方法—年齡在20-35岁之间的患者，其中51位是女性，21位是男性。患者随机分为两组，一组用布洛芬400mg治疗，另一组用顛茄6C治疗。患者各自服用自己組別的藥物兩次，並在他們於部門被套上的矯正分牙圈（歐姆分牙圈（Ormco Separators），歐姆可公司，美國加州）前一小時服用一劑，和在套上後6小時服用一劑。並以VAS評分記錄疼痛分數。VAS是一個以毫米為刻度的10厘米測量，每隔一段時間記錄他們的疼痛，記錄時間為套上後的兩小時、六小時、睡眠時間、第一天早上、第二天早上、第三天早上和第五天早上。

結果—事後比較顯示兩組在兩小時（ $p=0.77$ ）、六小時（ 0.073 ）、一天（ $p=0.120$ ）、兩天（ $p=0.283$ ）、三天（ $p=0.363$ ）、五天（ $p=0.622$ ）和七天之間是沒有差異。

結論—布洛芬和顛茄6C是有效的，兩者在提供適當鎮痛的統計上沒有顯著差異。使用顛茄6C沒有副作用，使之成為其中一種有效且可行的替代方案。

