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Original Article

บทวิทยาการ

Sedation, anxiolysis, and analgesia of midazolam orally administered in adult patients undergoing surgical removal of impacted molars

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Abstract

Objective To disclose the effects of midazolam in sedation, anxiolysis, and analgesia in healthy patients undergoing surgical removal of impacted mandibular third molars.

Materials and methods Each of 40 healthy patients having left and right impacted mandibular third molars underwent surgical removal in separate visits. A randomized double-blind placebo controlled method was used for prescription of a 7.5 milligram of midazolam tablet. After oral administration of the drug and local anaesthesia, the impacted teeth were removed surgically in a standard fashion. By means of an observation and visual analogue scale, the clinical effects of midazolam on sedation, anxiolysis and analgesia were investigated. The obtained data on the sedative effect were analyzed using a Chi-square test, and those of the rest using Wilcoxon Rank Sum test.

Results Despite their insignificances, some differences in the patients' sedative levels after taking midazolam were detectable and higher than the control groups. Mean values of their anxiety levels were also significantly less at the periods of 1- and 5-hour post-surgery. After local anaesthesia and 1-hour post-surgery, significantly lower levels of their pain perception were observed.

Conclusion For the patients undergoing surgical removal of impacted mandibular third molars, midazolam orally administered is clinically useful in sedation and lowering the anxiety level. In addition, midazolam should be orally administered 1-2 hours prior to surgery. When associated with a local anaesthetic agent, it provides a satisfactory outcome during operation. An observation on the patients' appearances might be clinically insufficient and a measurement of vital signs is needed when the drug is prescribed.

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Key words: *impacted mandibular third molars; midazolam; pain*

Introduction

Minor oral surgery causes a stressful status to patients.[1] Physiological conditions of the patients, particularly children, are changed at the commencement of appointment, pre-surgery, and during operation.[2-7] When an extraction is indicated in the patients with some systemic diseases and in the elderly, a special care is needed to relieve their stress and pain.[8]

Preparation for an oral surgery leads to a success in the mental and physical management of the patients. A number of reports have shown satisfactory outcomes by the use of drugs,[9-11] and those of midazolam were already revealed.[12-14]

An impacted mandibular third molar needs a surgical removal and are most frequent in the 20- to 35-year-old group.[15] An oral administration of midazolam is convenient and suitable for a dentist in the private sector who performs surgical removal of the impacted teeth. Among several investigations of the clinical effects of midazolam prescribed to patients, most of them were performed in children, elderly, or patients with systemic diseases, while those in healthy adults are scarced. It was thus the prime objective of this study to disclose the sedative, anxiolytic, and analgesic effects of midazolam administered orally in healthy adults undergoing surgical removal of the impacted mandibular third molars.

Materials and methods

The research protocol had been reviewed by the Ethics Committee for Human Research of Naresuan University (NU), and the study was carried out at NU's Dental Hospital between June 2003 and January 2004. Participants were healthy individuals with no systemic diseases, had no allergic history of benzodiazepine, and had impacted mandibular third molars on both sides. After a detailed explanation of the study and the surgical procedures, informed written consent from 40 patients was obtained. Each patient had both impacted teeth removed surgically by the same operator, but on separate occasions with at least four weeks between them.

Pre-operative procedures

Neither food nor water was allowed pre-surgically at least 4 and 2 hours, respectively. Biostatistic data, chief complaint, medical history, past dental history of the patients were recorded. A radiographic image of the impacted tooth was taken by a paralleling technique, using a dental periapical film size 2 (Kodak®; Eastman Kodak Company, New York, USA) and a standard X-ray machine (Gendex® model 46-158800G4; Gendex Corporation, Illinois, USA). The patients' vital signs were recorded. Their anxiety level was objectively assessed by evaluating their appearances.

Prescription of the drug used in this study was done by a randomized double-blind placebo controlled method, i.e. a patient received a 7.5 milligram tablet of midazolam (Dormicum®; Bangkok, Thailand) in one surgical visit and a placebo in the other. The patients or operators had no access to the information. Thirty minutes after oral administration of the drug or placebo, their vital signs were recorded. In addition, the patients' anxiety level was assessed by the same assisting person using a chart with scales ranging from 1 (no anxiety) to 10 (extreme anxiety).

Operative procedures

Under a careful supervision of one oral and maxillofacial surgeon, all surgical procedures were similarly performed by the fifth or the sixth year dental students. Using 2% mepivacaine hydrochloride containing 1:100,000 epinephrine, inferior alveolar nerve block and long buccal nerve infiltration were obtained. The starting time of surgical processes was recorded.

An incision was performed originating at a point about 1.5 cm. distal to mandibular second molar. It was either ended at the distobuccal line angle of the impaction observable in the oral cavity or extended to the distobuccal line angle of the second molar if the impaction was clinically invisible. All incision lines were on the bone and followed each molar's cervical line. After elevation of the periosteum, bone surrounding the impaction was removed with a steel round bur in a handpiece. Bone removal procedure was performed under an irrigation with normal saline solution. In some cases, the impacted tooth was splitted by using a tungsten fissure bur and a straight elevator and then removed. The sockets were inspected and curetted to remove granulation tissues and dental sac. The surgical wound was then irrigated with normal saline solution. Flap approximation was performed and sutured with 3-0 black silk. A gauze pack was pressed against the operative site.

All mentioned variables and pain perception of the patients were objectively investigated after local anaesthesia, and at the 1st, 3rd and 5th hour after surgery.

Post-operative procedures

The patients were asked to bite on the gauze for 60 minutes and post-surgical care was instructed. Fifteen tablets of 400 milligram ibuprofen (Ibrofen 400 FC®; T.O. Chemicals Ltd., Bangkok, Thailand) were prescribed to each patient. On the seventh day post-surgery, the patients had their surgical wound inspected and sutures removed.

Statistical analyses

All data were analyzed using SPSS for Window version 10.0 statistical package. Intergroup differences and data on sedation were verified with a Chi-square test, and the patients' anxiety and pain with Wilcoxon Rank Sum test. In each test, the level of significance was set at .05.

Results

As shown in Table 1, 45% of the patients were male while the rest were female, and their mean age was 23.43 years. Eighty impacted mandibular third molars were removed. Mean surgical time was 72.34 minutes at the site where midazolam had been prescribed and 71.68 minutes where placebo had been used. At $p < .05$, no statistical difference in their mean surgical time was found.

After oral administration of midazolam and then local anaesthesia, some patients became drowsy with their eyes still opened. Despite their insignificant difference, the patients taking midazolam showed a higher sedative level than the patients with placebo. As the operation was started and prolonged, a number of patients who had midazolam were in a deeper level of sedation, i.e. became drowsy and responded either to verbal command or to stimulation. When compared to those provided with placebo, their sedative levels were significantly higher during surgery, at 1-, and at 3-hour post-surgery (Table 2).

The patients with midazolam possessed higher anxiety levels from the commencement of information collection until after anaesthetizing procedure (Table 3). Mean values of their anxiety levels were less than those provided with placebo. Significant differences in anxiety levels at the periods of 1- and 5-hour post-surgery were seen, when compared with those at other surgical time.

When compared to the group with placebo, the patients with midazolam possessed significantly lower mean values of pain perception after local anaesthesia and at 1-hour post-surgery (Table 4).

Table 1 Summary of the baseline data

Variable		Study group	
		Midazolam (n=40)	Placebo (n=40)
Gender	Male	n=18 (45.0%)	
	Female	n=18 (45.0%)	
Age (year)	Range	18.0-30.0	
	Mean standard deviation	24.43±3.10	
Surgical time (minutes)		72.34±20.23	71.68±21.75

Table 2 Summary of the patients' degree of sedation

Observation time	Study group	Score					Total	*p*-value
		1	2	3	4	5		
Pre-administration of drug	Midazolam	40	0	0	0	0	40	.346
	Placebo	40	0	0	0	0	40	
30 minutes post-administration of drug	Midazolam	28	11	1	0	0	40	.223
	Placebo	31	9	0	0	0	40	
After local anaesthesia	Midazolam	23	14	2	1	0	40	.076
(40 minutes post-administration of drug)	Placebo	30	7	3	0	0	40	
During surgery	Midazolam	18	14	7	1	0	40	.021*
	Placebo	29	8	3	0	0	40	
Surgical completion	Midazolam	20	11	7	2	0	40	.183
(90 minutes post-administration of drug)	Placebo	26	11	3	0	0	40	
1 hour post-surgery	Midazolam	9	13	14	4	0	40	002*
	Placebo	22	14	3	1	0	40	
3 hours post-surgery	Midazolam	4	10	7	19	0	40	.013*
	Placebo	11	15	3	11	0	40	
5 hours post-surgery	Midazolam	12	8	3	17	0	40	.309
	Placebo	10	15	3	12	0	40	

Score 1 = Fully conscious condition
Score 2 = Relaxed condition
Score 3 = Drowsiness and response to verbal command
Score 4 = Drowsiness and response to stimulation
Score 5 = Drowsiness and no response to stimulation
* Significant difference between two groups at $p < .05$

Table 3 Summary of the patients' degree of anxiety

Observation time	Study group	Mean	Standard error	*p*-value
Pre-administration of drug	Midazolam	3.295	0.522	.321
	Placebo	3.015	0.453	
30 minutes post-administration of drug	Midazolam	2.905	0.408	.359
	Placebo	2.775	0.443	
After local anaesthesia	Midazolam	3.150	0.459	.446
(40 minutes post-administration of drug)	Placebo	2.975	0.405	
During surgery	Midazolam	2.240	0.405	.200
	Placebo	2.593	0.386	
Surgical completion	Midazolam	1.205	0.290	.319
(90 minutes post-administration of drug)	Placebo	1.405	0.373	
1 hour post-surgery	Midazolam	1.343	0.280	.012*
	Placebo	2.220	0.360	
3 hours post-surgery	Midazolam	1.635	0.344	.133
	Placebo	2.023	0.345	
5 hours post-surgery	Midazolam	0.982	0.288	.043*
	Placebo	1.438	0.290	

* Significant difference between two groups at $p < .05$

Discussion

To reduce any bias to the results, all cases in this study were treated as independent variables because the factors relating to their teeth were individual (radiograph, tooth position, tooth morphology, and the surgeon), and the two teeth were removed at separate occasions.

Compared with other drugs in benzodiazepine group as for example diazepam and temazepam, midazolam[16] causes an anterograde amnesia. It also possesses a shorter duration of action, half-life, and recovery time. The clinical efficacy of midazolam has already been confirmed.[17-19] The oral administration of midazolam is convenient and can easily be accepted by the patients. Nevertheless, this administrative route provides uncertainly clinical outcomes. In contrast, the intravenous route gives expectable outcomes, despite its complexity and the need on a more careful attention. Since the dental students were involved in all surgical procedures, our patients were prescribed with midazolam alone and took the drug via the oral route.

Table 4 Summary of the patients' pain perception

Observation time	Study group	Mean	Standard error	*p*-value
Pre-administration of drug	Midazolam	Unobserved	Unobserved	Not
	Placebo	Unobserved	Unobserved	available
30 minutes post-administration of drug	Midazolam	Unobserved	Unobserved	Not
	Placebo	Unobserved	Unobserved	available
After local anaesthesia	Midazolam	2.275	0.316	.026*
(40 minutes post-administration of drug)	Placebo	2.907	0.352	
During surgery	Midazolam	1.563	0.305	.467
	Placebo	1.693	0.355	
Surgical completion	Midazolam	1.450	0.387	.218
(90 minutes post-administration of drug)	Placebo	1.788	0.445	
1 hour post-surgery	Midazolam	2.445	0.356	.003*
	Placebo	3.778	0.375	
3 hours post-surgery	Midazolam	3.715	0.398	.128
	Placebo	4.245	0.330	
5 hours post-surgery	Midazolam	2.655	0.368	.063
	Placebo	3.335	0.366	

* Significant difference between two groups at $p < .05$

Theoretically, the actions of midazolam are clinically visible approximately 30 minutes after oral administration. In this study, the patients still showed a sign of drowsiness with opened eyes after local anaesthesia. The duration of which was longer than 30 minutes after having already taken midazolam. This may be explained by our prescription of midazolam without any weight-related adjustment of the drug prior to the surgical procedure. An experiment performed in pre-school children showed a suitable dose of an oral midazolam to be 0.05 milligram per kilogram body weight, prior to a Class II amalgam restorative procedure.[20] A current investigation in an adolescent undergoing the plastic surgery revealed a dose of 7.5 milligram of midazolam to result in the best clinical efficacy.[21] Concerning the patients' age and the type of dental treatment, it is likely that an adolescent requires a higher dose before surgical removal of an impacted tooth. Nonetheless, an inversed correlation between midazolam dosage and the patients' advancing age has

been reported.[21] Taken into considerations upon the tooth-relating operation, an attention should be put on the dosage of midazolam pre-surgically prescribed to obtain a satisfactory level of sedation.

During local anaesthetic injection, patients showed a sign of irritation. However, it was decreased during operation and at the completion of surgical procedures. In the patients undergoing dental extraction, their vital signs were undoubtedly altered in accordance with the surgical times. Interestingly, a higher mean of heart rate was detected during making an appointment for a dental extraction.[3] Moreover, a higher systolic blood pressure was detectable during waiting for a dental treatment.[22] Similarities and discrepancies between other studies' results and ours need further explorations, albeit attributable to the methods of investigation and interpretation. We failed to collect all patients' vital signs, resulting us to present only the results from an objective observation on their appearances. On the other hand, other investigators recorded the patients' vital signs, the nature of which is physiologically measurable. It implied that an objective observation on the patient's appearances might partially facilitate an interpretation of the data.

The patients with midazolam decreased their pain perception after local anaesthesia until the surgical completion. It was then increased at 1- and 3- hours after the operation. This result could be explained by the pharmacological effects of both midazolam and the anaesthetizing agent used in this study. Pharmacologically, midazolam does not possess any analgesic property. Local anaesthesia is thus needed prior to any surgical procedures. Numerous studies have investigated clinical outcomes of midazolam in association with other drugs. Most of them disclosed clinically satisfied results on the usage of the combined intravenously infused during oral surgery.[23-26] It indicated that a combining usage of midazolam and other drugs is clinically useful. Nonetheless, it should be borne in the operator's mind that possible complications, particularly on respiratory system,[27] might be induced.

Conclusion

For the patients undergoing surgical removal of impacted mandibular third molars, midazolam orally administered is clinically useful in sedation and lowering the anxiety level. In addition, midazolam should be orally administered 1-2 hours prior to surgery. When associated with a local anaesthetizing agent, it provides a satisfactory outcome during operation. An observation on the patients' appearances might be clinically insufficient and a measurement of vital signs is needed when the drug is prescribed.

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การสงบประสาท การลดความวิตกกังวล และการลดความเจ็บปวดในผู้ใหญ่ที่ได้รับประทานไมดาโซแลมและเข้ารับการผ่าตัดฟันกรามคุด

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บทคัดย่อ

วัตถุประสงค์ เพื่อแสดงผลด้านการสงบประสาท การลดความวิตกกังวล และการลดความเจ็บปวด ของไมดาโซแลมในผู้ป่วยซึ่งมีสุขภาพแข็งแรงที่ผ่าตัดฟันกรามซี่ที่สามซึ่งคุดในขากรรไกรล่าง

วัสดุและวิธีการ ผู้ป่วยทั้ง 40 คนซึ่งมีฟันกรามซี่ที่สามซ้ายและขวาคุดในขากรรไกรล่าง ได้รับการผ่าตัดออกทีละซี่ในการนัดที่แตกต่างกัน การให้ไมดาโซแลมขนาด 7.5 มิลลิกรัมและยาหลอกนั้น ใช้วิธีการสุ่มแบบอำพราง หลังจากที่ผู้ป่วยได้รับประทานยาและถูกฉีดยาชาเฉพาะที่แล้ว ฟันกรามคุดได้ถูกผ่าตัดออก ผลทางคลินิกด้านการสงบประสาท การลดความวิตกกังวล และการลดความเจ็บปวดของไมดาโซแลม ได้ถูกตรวจสอบโดยการสังเกตและการใช้มาตราส่วนเชิงอุปมานด้วยสายตา หลังจากนั้น ตรวจสอบข้อมูลที่เกี่ยวกับการสงบประสาทด้วยการทดสอบไคสแควร์ และที่เกี่ยวกับการลดความวิตกกังวลและการลดความเจ็บปวดด้วยการทดสอบเชิงผลรวมและลำดับที่แบบวิลคอกซัน

ผลการศึกษา ระดับการสงบประสาทของกลุ่มที่ได้รับไมดาโซแลมสูงกว่าของกลุ่มควบคุมแต่ไม่มีนัยสำคัญทางสถิติภายหลังศัลยกรรมเป็นเวลา 1 และ 5 ชั่วโมงนั้น ค่าเฉลี่ยของระดับความกังวลของกลุ่มที่ได้รับไมดาโซแลมน้อยกว่าของกลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ นอกจากนี้ ยังพบว่า การรับรู้ด้านความรู้สึกเจ็บปวดของกลุ่มที่ได้รับไมดาโซแลมต่ำกว่าของกลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติหลังจากการให้ยาชาเฉพาะที่และ 1 ชั่วโมงภายหลังศัลยกรรม

สรุป การให้ผู้ป่วยซึ่งเข้ารับการผ่าตัดฟันกรามซี่ที่สามซึ่งคุดในขากรรไกรล่างรับประทานไมดาโซแลมนั้น เป็นประโยชน์ทางคลินิก ในแง่ของการสงบประสาทและการลดความวิตกกังวล นอกจากนี้ ควรให้ผู้ป่วยรับประทานไมดาโซแลมก่อนการผ่าตัดเป็นเวลา 1-2 ชั่วโมง เมื่อใช้ไมดาโซแลมร่วมกับยาชาเฉพาะที่แล้ว จะทำให้เกิดผลเป็นที่น่าพึงพอใจในระหว่างการผ่าตัด อย่างไรก็ตาม เมื่อมีการสั่งไมดาโซแลมให้แก่ผู้ป่วยกลุ่มนี้ การสังเกตการแสดงออกของผู้ป่วยอาจไม่เพียงพอในทางคลินิก และจำเป็นต้องวัดสัญญาณชีพของผู้ป่วย

(ว ทันต จุฬาฯ 2548;28:99-108)

คำสำคัญ: *ความเจ็บปวด; ฟันกรามซี่ที่สามซึ่งคุดในขากรรไกรล่าง; ไมดาโซแลม*