Effectiveness of Medium Chain Triglyceride Ketogenic Diet in Thai Children with Intractable Epilepsy

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Objective: *To determine the efficacy, side effects and feasibility of Medium chain triglyceride (MCT) ketogenic diet (KD) in Thai children with intractable epilepsy.*
Material and Method: *Children with intractable epilepsy were recruited. Baseline seizure frequency was recorded over 4 weeks before starting MCT KD. Average seizure frequency was assessed at 1 month and 3 months, compared to the baseline using Wilcoxon Signed Rank Test. Side effects and feasibility were also assessed by blood tests and an interview.*
Results: *Sixteen subjects were recruited with mean seizure frequency of 0.35-52.5 per day. After treatment, there was a significant reduction in seizure frequency, ranging from 12% to 100% (p = 0.002 at 1 month, and 0.001 at 3 months). 64.3% of the subjects achieved more than 50% seizure reduction at 3 months and 28.6% of the patients were seizure-free. Common adverse effects were initial weight loss (37.5%)and nausea (25%). 87.5% of subjects and parents were satisfied with the MCT KD with 2 cases dropping-out due to diarrhea and non-compliance.*
Conclusion: *MCT ketogenic diet is effective and feasible in Thai children with intractable epilepsy. Despite modification against Asian culinary culture, the tolerability and maintenance rate was still satisfactory. A larger study is required.*

Keywords: *Medium chain triglyceride, Ketogenic diet, Children, Epilepsy, Seizure, Effectiveness*

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Epilepsy is one of the most common neurological disorders in children with the approximate incidence of 0.5-1% of allchildren under 16 years of age[1]. The mainstay of treatment is antiepileptic drugs and epilepsy surgery in selected cases. In those who are not surgical candidates, 47% respond to the first antiepileptic drug[2], 10% more are controlled by the second or third drug but the rest remains intractable despite a combination of multiple drugs used[3]. Despite several new drugs being developed so far, those with drug-resistant epilepsy are still suffering from uncontrolled seizures. Various side effects from polytherapyinevitably disturb cognitive function in children. Other treatment options including ketogenic diet and vagus nerve stimulation have been widely explored. Previous evidence has shown favorable outcome of KD in seizure control comparable to medication but no cognitive adverse effects[4-8], making these treatment modalities an additional benefit for those affected by excessive dose and type of antiepileptic drugs (AED).

Despite the reports of efficacy of ketogenic diet in western culture, the use of this treatment modality is still limited in Asian population[9], and the rate of long-term diet maintenance is low[10-12]. The major drawback probably includes diet refusal and difficult recipe owing to the fact that most Asian culinary culture is starch-based, in contrast to Ketogenic diet recipe which comprises high fat and limited carbohydrate. Most Asian studies, however, offer classic ketogenic diet with main fat source from Long-chain triglyceride (LCT)[10-12] which requires a high ketogenic-antiketogenic ratio (3:1-4:1) resulting in very limited amounts of staple food in Asian meals like rice or noodles. The authors aim to investigate the use of MCT that can produce better ketogenesis at lower ratio of 1.3-1.4:1. This formula should maintain good seizure control while allowing more carbohydrates in the patients' meals and may improve diet tolerability.

Material and Method

Children younger than 18 years old were

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included in pediatric neurology unit at King Chulalongkorn Memorial Hospital over 2010-2013. This study was approved by the institutional review board, and the children or their parents gave assent or consent to participate. The inclusion criteria was intractable epilepsy uncontrolled by at least 2 appropriate antiepileptic drugs and had no treatment change in the last 3 months. Those with progressive brain disorders, metabolic disorders contraindicated to KD, or being a candidate for, or having undergone epilepsy surgery or vagus nerve stimulation (VNS) were excluded.

The subjects were assessed for underlying condition, seizure type and frequency, Electroencephalography (EEG) and neuroimaging findings, existing co-morbidities, and nutritional status, and any contraindication for ketogenic diet at the screening visit. A seizures diary was recorded daily for each seizure type over 4 weeks as a control period without change of medication. Then, all subjects were admitted for ketosis induction by 18-hour fasting, then gradually titrated MCT KD formula to the final target. Total energy was restricted to 90% of Dietary Reference Intake (DRI) for age and sex. The formula comprised MCT oil (50%), Carbohydrate 10-15% and protein 1-2 g/kg per day according to DRI for age and sex, and the remaining composition was Long chain triglyceride (LCT) oil (30%).

Ketogenic diet was maintained at home without any change in antiepileptic drug for the first 3 months. Urine ketone, seizure frequency and adverse effects were recorded at home by the family, and reviewed at 1 and 3-month visits, then quarterly thereafter. A review for palatability, diet preparation feasibility, diet refusal and parental satisfaction was carried out at each visit or at diet discontinuation.

The primary outcome was seizure control and the secondary outcome was undesirable effects of the treatment. Regarding the seizure control, an average seizure frequency per day in the last 14 days for each subject was calculated at baseline and each visit. These values were compared at baseline, and at 1 and 3 months after treatment, using Wilcoxon Signed Rank test. The response of treatment was also calculated as percentage of seizure reduction based on the improvement in the average seizure frequency from baseline, and categorized into 4 groups: less than 50% seizure reduction, 50-90% seizure reduction, 90-99% seizure reduction and seizure freedom at 1 and 3 months.

The secondary outcome was assessed by change in nutritional status, side effects, and treatment satisfaction to the family. Weight, height were measured, and body mass index (BMI) and BMI Z-score were calculated at baseline, 1 month, and 3 months. These were compared using Wilcoxon Signed Rank Test. Adverse effects were evaluated both clinically and by laboratory including complete blood count, electrolytes, uric acid, Calcium, Phosphate, liver function, renal function, lipid profile and urine Calcium/ Creatinine ratio. Feasibility of MCT KD and parental dissatisfaction were assessed at each visit and the overall adherence rate to KD was calculated at 3 months.

Results

Demographic and epilepsy data

16 subjects (3 males, 13 females) were recruited with age range of 0.5-16 years (6.295$\pm$4.820 years, Median 5.41 years). 62.5% had multiple seizure types as shown in Table 1, with generalized tonic clonic (GTC) being the most common (93.75%), followed by tonic (56%), focal, myoclonic, atonic (12.5% each) and absence (12.5%). Regarding the syndromic diagnosis, 10 cases (62.5%) had Lennox-Gastaut syndrome (LGS), 4 cases (25%) had idiopathic generalized epilepsy, and 2 cases (12.5%) had focal epilepsy. The average seizure frequency ranges from 0.35 to 52.5 seizures per day (median 4.14 seizures per day). All subjects had abnormal EEG finding (18.8% was focal and 81.2% was generalized epilepti form discharge). 8 of 13 cases (61.5%) with neuroimaging showed abnormal results. All case were drug-resistant, using 2-7 antiepileptic drugs (median = 3).

Seizure outcome

The average seizure frequency at baseline, 1 month and 3 months post treatment for each subject are shown in Table 2. The seizure frequency reduced significantly at both 1 month (p-value = 0.002) and 3 months (p-value = 0.001). Fifteen patients had seizure reduction except Subject number 15 who had an increase in seizure frequency. The family was unable to control carbohydrate intake from extra snacks, causing poor ketosis maintenance so they decided to discontinue MCT KD after 1 month due to non-compliance. Another subject (number 8) also stopped the treatment prematurely after 1 month when he had acute diarrhea at home. Therefore, these two cases were excluded from the 3-month evaluation.

Each subject was categorized according to the percentage of seizure reduction as shown in Table 3. 8 of 16 subjects (50%) showed more than 50% seizure reduction at 1 month (5 subjects achieved more than 90% seizure reduction). At 3-month visit, 64% of the

Table 1. Demographic and epilepsy data

Patient	Sex	Age (years)	Seizure types	Epileptiform discharge	Neuroimaging	AED
1	Female	6	Tonic, atonic	Focal	FCD	3
2	Female	1.7	Focal, GTC	Generalized	Normal	3
3	Female	16.3	Tonic, GTC, absence	Generalized	FCD	3
4	Female	10	GTC	Focal	FCD	4
5	Female	0.5	GTC	Generalized	Diffuse atrophy	4
6	Female	8	GTC, tonic	Generalized	N/A	4
7	Female	6	GTC, tonic, myoclonic	Generalized	Normal	3
8	Female	13.1	Focal, GTC, tonic	Focal	Bilateral hippocampal sclerosis	2
9	Female	2.2	GTC, tonic	Generalized	Diffuse atrophy	4
10	Male	4.8	GTC, tonic	Generalized	Diffuse atrophy	3
11	Male	13	GTC	Generalized	Diffuse atrophy	4
12	Male	7.3	GTC	Generalized	Normal	2
13	Female	3.6	GTC, tonic	Generalized	Normal	4
14	Female	2.0	GTC, tonic	Generalized	N/A	7
15	Female	2.4	GTC	Generalized	N/A	2
16	Female	2.2	GTC, atonic, myoclonic	Generalized	Normal	5

FCD = Focal cortical dysplasia; N/A = Not available (no neuroimaging done)

Table 2. Average Seizure frequency and Percentage of seizure reduction before and after treatment

Subject number	Baseline	1 month post KD (n = 16)		3 months post KD (n = 14)	
	Seizure (times/day)	Seizure (times/day)	% seizure reduction	Seizure (times/day)	% seizure reduction
1	3.85	2.14	44	1.10	71
2	1.14	0.78	31	1.00	12
3	1.42	0.92	35	0.85	40
4	52.50	0	100	0	100
5	49.14	4.43	91	0	100
6	5.70	4.00	30	3.42	40
7	1.64	1.57	4	1.28	22
8	0.64	0.57	11	N/A	N/A
9	8.30	0.14	98	0.07	99
10	4.43	0.07	98	0	100
11	3.41	1.33	61	1.92	43
12	10.00	1.00	90	1.00	90
13	0.35	0.14	60	0.14	60
14	9.20	4.20	54	0	100
15	3.35	5.90	-76	N/A	N/A
16	10.60	6.00	43	0.02	99

Seizure = Average Seizure frequency; N/A = Not available due to early discontinuationfrom side effect or non-compliance

remaining 14 subjects had more than 50% seizure reduction and 50% of the subjects had more than 90% seizure reduction.

Nutritional and adverse effects

At baseline, BMI ranged between 8.86-22.66 (median 15.48) and BMI Z-score range was from -6.14

Table 3. Response to treatment classified by percentage of Seizure reduction

% seizure reduction	1 month post KD (n = 16)	3 month post KD (n = 14)
Not reduced	1 (6.25)	0
<50% seizure reduction	7 (43.75)	5 (35.72)
50-89% seizure reduction	3 (18.75)	2 (14.28)
90-99% seizure reduction	4 (25.00)	3 (21.43)
Seizure freedom	1 (6.25)	4 (28.57)

to 1.52 (median -1.09). 3 cases (18.75%) had malnutrition as defined by BMI-Z score more than -2. There was no statistically significant change in weight, height, BMI and BMI Z-score, when compared before and after treatment, with *p*-value at 1 month = 0.374, 0.528, 0.424, 0.445 and *p*-value at 3 months = 0.878, 0.171, 0.722, 0.959 respectively.

Adverse effects were reported in 80% of all subjects. This included initial weight loss (37.5%), nausea and vomiting (25%), metabolic acidosis (18.75%), hypercalciuria (12.5%), hyperlipidemia (6.25%), acute diarrhea (6.25%) and Iron deficiency anemia (6.25%). All were benign and recovered shortly after. Initial weight loss occurred in 6 cases but half regained their weight in 3 months. The others gained more weight with KD adjustment. Apart from hypercalciuria which was asymptomatic but treated by oral citrate to decrease the risk of renal stones, the other side effects also improved spontaneously or with KD adjustment. However, in subject number 8 with acute diarrhea, the parents decided to discontinue MCT KD despite full recovery in a short period without treatment.

The review for palatability, feasibility, and parental satisfaction after the initial 3 months showed that 2 subjects (12.5%) dropped-out due to diarrhea and non-compliance to carbohydrate restriction. None of the 16 families had no concern regarding palatability, diet refusal or difficult preparation. The remaining 14 subjects including those with less than 50% seizure reduction chose to continue MCT KD after the 3-month evaluation period. There was no further withdrawal and 81.25% remained on MCT KD at 12-month visit. There was one patient death from massive hemoptysis due to congenital systemic to pulmonary vascular anastomosis at 4 months after MCT KD. After 1 year, another patient expired from proven viral myocarditis (not related to treatment) and 5 of the remaining 12 cases (41.6%) decided to discontinue MCT KD, all from non-compliance. Only 4 cases continued until or beyond 2 years during the study period.

Discussion

The results showed that MCT KD was an effective treatment of intractable epilepsy in Thai children. Similar to previous overseas reports on KD[4-8], it can be used in various age, seizure types and either in focal or generalized epilepsy. In this study, MCT KD significantly reduced mean seizure frequency and approximately two-third of the cases had more than 50% seizure reduction which was considered clinically significant. Comparing to previous studies from western countries[4-8,13-20], the percentage of more than 50% seizure reduction ranged between 38-67.3% which is not different from this study. However, those studies were mostly conducted with classical ketogenic diet which mainly used LCT as the main fat source, differing from this study which used MCT formula.

As the western diet has a high fat component, the use of KD is easily adapted into daily recipes at home but more limitation of sugar and starch. On the contrary, the main food staples in Asian cultures are rice and noodles. This usually leads to the concern about poorer compliance from significant diet modification and more difficulty for parents in diet preparation as LCT KD requires a precise calculation to prepare the exact amount of carbohydrate and fat for each meal. A previous study of classical KD in Thailand[12] showed good efficacy with 62.5% having more than 90% seizure reduction, but a short average duration of 7.67 months on KD. Likewise, the seizure reduction in this study was also significant, but the dropout rate was low with 80% still on KD at 1 year. This is probably from the less carbohydrate restriction and easier preparation of MCT oil which can be added directly into food or supplementary drinks. However, there was no previous study of MCT KD in Thailand to compare with this study.

Seizure reduction were seen at 1 month and, in some patients, could be very early in the first week. Notably, many patients continued to improve in seizure reduction at 3 months and 3 more cases became seizure-free without change of diet formula or medication. This was clinically correlates with an increase in urine ketone. 4 of 7 cases (57.1%) who had more than 90% seizure reduction were LGS cases with multiple seizure types that were drug resistant. Good seizure control in this particular syndrome were also observed in other western studies offering classical KD[21,22]. After 3

months, most subjects who were not seizure-free underwent ketogenic ratio or AED adjustment to improve seizure control. Therefore, seizure reduction beyond 3 months was not included here even though many cases benefited from additional KD or AED adjustment.

Regarding the adverse events, minor events were seen in many cases (80%). Gastrointestinal and metabolic effects were common with nausea/vomiting and poor weight gain being the most frequent (25%). Most required no treatment in the first 3 months, and minor dietary adjustment or nutritional supplement mostly solved the problems. There was no report on negative cognitive effect. In fact, some even reported more alertness and cognitive response. This may be due to an improvement in seizure control, interictal epileptiform discharge[23], and reduction of medication in some cases. Similar improvements in cognition were also seen in the previous studies[24,25].

Most parents found MCT KD feasible and satisfactory with no concern about preparation or feeding. The retention rate was high at 3 months and 1 year (87.5% and 81.25% respectively) comparing to another study in China which showed a retention rate of 62.8% at 3 months and 24.4% at 12 months[10]. However, one case discontinued because of acute diarrhea after one month which was more likely to be an acute infection than the side effect of KD. This actually reflects strong parental concerns over the side effects which might have been overcome by an adequate support from the team. The other case lost ketosis as his parents were unable to control snack consumption. This also reveals the importance of continuous and real-time support from a multidisciplinary team to help the families go through unfortunate events with the sick rules or party rules for KD. Once the family passes the initial period, the adherence to the diet seems easier as most in the study continued on for a year. However, the non-compliance rate after 1 year again emphasizes the need for support to maintain KD even in experienced family who can improvise the recipes to suit the needs of their child.

This is the first prospective study of MCT KD in Thailand which specifically proved the effectiveness in the context of Thai dietary culture. The limitation of this study is the small number of subjects. A larger, randomized study is required to endorse these findings.

Conclusion

MCT ketogenic diet is a potential treatment for Thai children with intractable epilepsy. The seizure control of KD is comparable to other treatment options. Despite major diet modification, the feasibility and tolerability were satisfactory. Adverse effects are mild and easily solved. A larger study with longer follow-up is required.

What is already known on this topic?

Ketogenic diet is effective and widely used for treatment of pediatric epilepsy in western countries. The centers that provide this service in Asian and Thailand are still limited. The only published study in Thailand based on classical LCT ketogenic diet, which showed effectiveness but a short maintenance duration of KD.

What this study adds?

This is the first prospective study of MCT ketogenic diet in Thai children to prove effectiveness and feasibility of this potential treatment.

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Potential conflicts of interest

None.

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ประสิทธิผลการควบคุมโรคลมชักในเด็กด้วยอาหารคีโตนชนิด medium chain triglyceride

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วัตถุประสงค์: เพื่อศึกษาประสิทธิผลผลการควบคุมชักด้วยอาหารคีโตนในรูป medium chain triglyceride (MCT) ในผู้ป่วยเด็กไทยที่ดื้อต่อยากันชัก รวมถึงผลข้างเคียงและความยอมรับได้ของครอบครัว

วัสดุและวิธีการ: ผู้ป่วยเด็กโรคลมชักที่ดื้อต่อยากันชัก ที่เข้าร่วมโครงการได้รับการบันทึกความถี่การชักเป็นเวลา 4 สัปดาห์ก่อนเริ่มการรักษาด้วย MCT ketogenic diet แล้วจึงนัดตรวจติดตามเพื่อวิเคราะห์เปรียบเทียบความถี่การชักเฉลี่ยก่อนและหลังการรักษา 1 เดือนและ 3 เดือนโดย Wilcoxon Signed Rank Test และวิเคราะห์ผลข้างเคียงและความยอมรับได้ของครอบครัว

ผลการศึกษา: ผู้ป่วยที่เข้าร่วม 16 ราย มีความถี่การชักเฉลี่ย 0.35-52.5 ครั้งต่อวัน ผู้ป่วยมาตรวจติดตามต่อเนื่องที่ระยะเวลา 1 เดือนทั้งหมด 11 รายและที่ 3 เดือนทั้งหมด 10 ราย (ผู้ป่วยขอหยุดการรักษา 1 รายเนื่องจากอาการถ่ายเหลว) ผู้เข้าร่วมวิจัยมีการชักลดลงอย่างมีนัยสำคัญทางสถิติ ($p = 0.002$ ที่ 1 เดือนและ 0.001 ที่ 3 เดือนหลังได้รับการรักษา) โดย 64.3% มีการชักลดลงมากกว่า 50% และ 28.6% ไม่มีการชักเลยที่ 3 เดือน ผลข้างเคียงที่สำคัญได้แก่ น้ำหนักลด 37.5% คลื่นไส้อาเจียน 25% อย่างไรก็ดีผู้ป่วยและครอบครัว 87.5% ไม่พบความลำบากเชิงปฏิบัติ แต่ครอบครัวผู้ป่วย 2 รายขอยุติการรักษาก่อนกำหนดจากอาการถ่ายเหลวและไม่สามารถควบคุมอาหารได้

สรุป: MCT ketogenic diet มีประสิทธิผลในการรักษาผู้ป่วยเด็กไทยที่ดื้อต่อยากันชักแม้จะพบผลข้างเคียงที่ไม่รุนแรงบ้างและผู้ป่วยสามารถยอมรับปฏิบัติได้อยู่ในเกณฑ์น่าพอใจแต่ยังต้องการการศึกษาเพิ่มเติมในผู้ป่วยจำนวนมากขึ้นและติดตามผลระยะยาวขึ้นต่อไป