Original Article

موضوع أصيل

COMPARISON OF LOCALLY PREPARED VERSUS INDUSTRIALLY PRODUCED THERAPEUTIC MILK FOR MANAGEMENT OF SEVERE ACUTE MALNUTRITION IN BASRA

مقارنة الحليب العلاجي المحضر محلياً مع الحليب المنتج صناعياً في معالجة حالات سوء التغذية الشديد الحاد في البصرة

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ملخص البحث

هدف البحث: تم إجراء هذه الدراسة الوصفية الراجعة لتقييم فعالية الحليب العلاجي F75 و F100 المحضر محلياً مع الحليب المنتج صناعياً ودراسة تأثيراته ونتائجه الملاحظة عند المرضى.

طرق البحث: تم جمع البيانات العائدة لـ264 من الأطفال والرضع أعمارهم بين 1-36 شهراً لديهم حالات سوء تغذية حاد شديد وذلك في قسم إعادة التأهيل التغذوي خلال الفترة بين شهري أيار 2013 وكانون الأول 2014. تم اعتماد معايير القبول والمعالجة المعتمدة حسب توصيات منظمة الصحة العالمية WHO. توافر الحليب المحضر صناعياً بدءً من شهر أيار 2013 وحتى آذار 2014 ومن ثم تم استخدام الحليب البديل حتى نهاية شهر كانون الأول 2014.

النتائج: خضع 159 طفلاً للمعالجة بالحليب المحضر صناعياً (F75 و F100) وقد شكلوا المجموعة 1، في حين خضع 105 أطفال للمعالجة بالحليب المحضر محلياً (المجموعة 2). بلغ متوسط أعمار المرضى 9.91 شهراً، في حين بلغ متوسط الوزن 5.362±1.913 كغ. كانت جميع الحالات المقبولة هي حالات اختلاطات لسوء تغذية شديد حاد، مشعر الوزن للطول (نقاط z) كانت ≤3 SD و≤4 SD عند 33.3% و21.6% على الترتيب، في حين لوحظ وجود وذمة عند 6.4% فقط من المرضى، كما أن 44.7% من المرضى هم رضع دون 6 أشهر من العمر وبحالة شديدة من الهزال (بنسبة 50.9% و35.2%) في المجموعتين 1 و2 على الترتيب دون وجود فارق إحصائي مهم. من خلال مقارنة مشعرات التأثيرات العلاجية للحليب المحضر صناعياً والمحضر محلياً لوحظ أن متوسط الوزن هو (5.107±1.79 و5.749±2.064 كغ على الترتيب)، نسبة حدوث زيادة جيدة أو متوسطة في الوزن (71.4 و71% في المجموعتين على الترتيب)، ومدة البقاء في المشفى وحدوث الوفاة لم تظهر فروقات هامة إحصائياً بين مجموعتي الدراسة. بلغت نسبة الوفيات في مركز إعادة التأهيل 5.67% وقد شكل إنتان الدم 60% من حالات الوفاة الإجمالية، مع زيادة حدوث الوفاة لدى حالات ضعف اكتساب الوزن وحالات الهزال الشديد وبفارق هام من الناحية الإحصائية (قيمة p تعادل 0.008 و0.000 على الترتيب).

الاستنتاجات: يتمتع الحليب F75 و F100 المحضر محلياً بالفعالية العلاجية نفسها للحليب المحضر محلياً صناعياً في تدبير حالات سوء التغذية الشديد.

ABSTRACT

Objective: *A retrospective descriptive study was carried out to evaluate the therapeutic effectiveness of F75 and F100 prepared locally in comparison to industrially produced milk and its relation to their outcome.*

Methods: *Data of 264 infants and children aged 1-36*

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months with severe acute malnutrition in the nutrition rehabilitation ward; were analyzed during the period from May 2013 till December 2014. The admission criteria and treatment plan was according to World Health Organization guidelines. The industrially produced milk was available from May 2013 till March 2014 then locally prepared milk was used as alternative till the end of December 2014.

Results: *One hundred fifty nine patients received industrially produced F75 and F100 (group 1) and (105) patients received locally prepared therapeutic milk (group 2) were studied; their mean ages are 9.91 months and mean weight was 5.362±1.913. All admitted children were complicated cases of severe acute malnutrition; weight for height Z score; ≤3SD and ≤4SD is 33.3% and 21.6% respectively, only 6.4% of admitted patients have edema, and 44.7% are infants under 6 months of age with severe wasting as criteria for admission with (50.9%, 35.2% in group 1 and 2) with statistically significant result. Females and males distribution was 55.7% and 44.3% respectively. Comparison of indicators for monitoring therapeutic effect of industrially and locally prepared formula shows that the mean weight ± SD is 5.107±1.79, 5.749±2.064 respectively, good and moderate weight gain is recorded in 71.4% and 71%, duration of hospitalization and death show no significant differences in both groups. The mortality in nutrition rehabilitation centre is 5.67% and sepsis constitutes 60% of all deaths with high frequency of death recorded in patients with poor weight gain and those with severe wasting; with significant result of p-value, 0.008 and 0.000 respectively.*

Conclusions: *Locally prepared F75 and F100 formula has the same therapeutic effect as the industrially produced F75 and F100 in the management and outcome of patients with severe malnutrition.*

INTRODUCTION

Severe acute malnutrition (SAM) is a major cause of mortality and morbidity in children under five years of age in developing countries.[1] In the period 2011-2013, the precentage of children younger than 5 years of age; in developing countries and in the least-developed countries who suffer from moderate to severe malnutrition seen in was 14% and 25% respectively; the highest rates of moderate-severe malnutrition seen in South Asia and West Central Africa, 42% and 23%, respectively.[2]

With proper management of severe acute malnutrition in nutrition rehabilitation center (NRC) and follow up care; the lives of many children could be saved and the case fatality rate can be decresed from over 30% to less than 5%.[1]

Standardized case management protocol as suggested by World Health Organization (WHO): appropriate feeding, micronutrient supplementation, antibiotic therapy, intravenous fluid for shock state, ReSoMal solution for rehydration and careful management of complications.

Feeding is a critical part in management of SAM, in the stabilization phase cautious approach is required because of the child's fragile physiological state and reduced homeostatic capacity. Feeding should be started as soon as possible after admission and should be designed to provide just sufficient energy and protein to maintain basic physiological processes. Milk-based formulas such as starter F75 containing 75 kcal/100 ml and 0.9 g protein/100 ml will be satisfactory for most children. In the rehabilitation phase a vigorous approach to feeding is required to achieve very high intakes and rapid weight gain of >10 g/kg/day. The recommended milk-based F100 contains 100 kcal and 2.9 g protein/100 ml.

The composition of pre-packaged F75 and F100 prescribed by training manual of WHO and several recipes are given; that provide energy and protein needed for stabilization and catch up. The choice of recipes may depend on the availability of ingredients particularly type of milk and cooking facilities.[1]

METHODS

The data of admitted children to the nutrition rehabilitation ward with SAM were analyzed retrospectively from 1 of May 2013 till 31 of December 2014 and divided into two groups. The reviewed data is: age, sex, Z score, weight on admission and discharge,

weight gain, duration of hospitalization, clinical diagnosis on admission and their outcome.

One hundred fifty nine patients receive industrially produce F75 and F100 (group 1) and 105 patients receive locally prepared therapeutic milk (group 2). The industrially produced milk was available from May 2013 till March 2014 then locally prepared milk was used as alternative till the end of December 2014.

The preparation of F75 and F100 recipes was based on local source ingredients. The recipes of F75 include cereal flour require cooking prescribed for SAM with diarrhea: dried whole milk 35 g, sugar 70 g, cereal flour 35 g, vegetable oil 20 g, and locally prepared mineral mixture 20 ml and added water to make 1 liter.

F100 ingredients include:dried whole milk 110 g, sugar 50 g, vegetable oil 30 g, mineral mix 20 ml and added water to make 1 liter.

The contents of the mineral mix are potassium chloride, tri-potassium citrate, magnesium chloride, copper sulphate and zinc acetate already prepared in the ward. Diluted F100; special therapeutic formula especially prepared for infants <6 months or infants > 6 months weigh < 4 kg without edema, prepared by adding 35 ml of clean water to 100 ml of F100 already prepared to have 135 ml diluted F100.[3] Preparation of therapeutic milk need staff, time and kitchen facilities while commercial therapeutic milk preparation sourced from Nutriset, France which is more easily prepared; just mixing powder with measured water.

Our aim is to evaluate the therapeutic effectiveness of F75 and F100 prepared locally in comparison to industrially produced milk in management of severe SAM as well as study some selected variables of malnourished patients.

RESULTS

Data of 264 infants and children with severe acute malnutrition (SAM) who were admitted to nutrition rehabilitation ward analyzed; their ages ranged from 1-36 months and mean age was 9.91 months with standard error 0.479.

Females and males distribution are 55.7% and 44.3% respectively with frequency of patients according to their age group shows that 44.7% are infants below six months of age, and 73.1% are below twelve months.

One hundred fifty nine patients receive industrially produce F75 and F100 (group 1) and 105 patients receive locally prepared therapeutic milk (group 2). Distribution of age and sex reveals that higher frequency of infants <6 months (50.9%, 35.2%) in 2013 and 2014 with significant result as shown in Table 1.

Variables		Group1*	Group2**	p-value
		No. (%)	No. (%)	
Age groups (months)	<6	81 (50.9%)	37 (35.2%)	0.03
	6-12	37 (23.2%)	38 (36.2%)	
	12-24	34 (21.4%)	22 (21.0%)	
	24-36	7 (4.4%)	8 (7.6%)	
Sex	Females	94 (59.1%)	53 (50.5%)	0.2
	Males	65 (40.9%)	52 (49.5%)	
Total		159 (100%)	105 (100%)	

*Patients receive industrial therapeutic milk
**Patients receive locally prepared milk

Table 1. Age and sex distribution in group 1 and group 2.

Table 2 shows reviewed data of clinical presentation of malnourished children reveals high frequency of pneumonia and acute diarrhea (30.3% and 27%) respectively. Mean days of hospitalization is 6.829±4.45; ranged from 1-30 days with median 6.00 days and mean (weight±SD) on admission and discharge was 5.362±1.913, 5.664±1.957, respectively.

Main Clinical Presentation	No. (%)
Acute diarrhea	73 (27 %)
Chronic diarrhea	35 (13.25%)
Pneumonia	80 (30.3%)
Poor weight gain	33 (12.5%)
UTI	16 (6 %)
Sepsis	20 (7.57)
Others	7 (2.6%)
Total	264 (100)

Table 2. Clinical presentation of malnourished children admitted to NRC.

	Variables	No.	(%)
Z Score	≤ -3 SD	88	33.3
	≤ -4 SD	41	15.5
	Severe wasting	118	44.7
	Edema	17	6.4
Duration of hospitalization	Mean±SD	6.829±4.452	
	1-7	181	68.6
	7-14	69	26.1
	14-21	9	3.4
	21-30	5	1.9
Weight gain g/kg/day	Good (>10)	125	47.3
	Moderate (5-10)	63	23.9
	Poor (<5)	76	28.8
Mortality		15	5.68
Total		264	100

Table 3. Selected variables of studied patients.

Variables	Group 1	Group 2	p-value
Weight	5.107±1.79	5.749±2.064	0.22
Duration of hospitalization	6.66±4.56	7.085± 4.276	0.76
	No. (%)	No. (%)	
1-7	113 (71.06)	68 (64.76)	0.66
7-14	39 (24.52)	30 (28.57)	
14-21	4 (2.51)	5 (4.76)	
21-30	3 (1.88)	2 (1.9)	
Weight gain (gram/kg/day)	No. (%)	No. (%)	
Good (>10)	73 (45.9)	52 (49.5)	0.79
Moderate (5-10)	40 (25.2)	23 (21.9)	
Poor (<5)	49 (28.9)	30 (28.6)	
Death	9 (5.66)	6 (5.7)	
Total	159	105	

Table 4. Comparison of indicators for monitoring therapeutic effect of locally prepared versus industrial therapeutic milk.

Only 6.4% of admitted patients have edema, and 44.7% are infants under 6 months of age with severe wasting as criteria for admission; as well as the duration of hospitalization in 68.6% of patients is 1-7 days and only 5 patients stay for >3 weeks. Good and moderate weight gain reported in (47.3%, 23.9%) respectively, Table 3.

Some selected variables of patients receive industrial therapeutic milk (Nutriset) (Group 1); and patients receive locally prepared milk (Group 2); as mean weight, duration of hospitalization, weight gain and death are studied in Table 4 which shows no statistically significant differences of studied variables.

Death is studied in relation to some selected variables as weight gain, duration of hospitalization and Z score is shown in Table 5. High frequency of death recorded in children with poor weight gain as well as those with Z score ≤ -4 SD, with significant result; p-value was

		No.	Death (15)	Total	p-value
Weight gain	Good	123	2 (1.6)	125	0.008
	Moderate	59	4 (6.3)	63	
	Poor	67	9 (11.8)	76	
Duration of hospitalization	1-7	168	13 (7.1)	181	0.45
	7-14	67	2 (2.8)	69	
	14-21	9	0	9	
	21-30	5	0	5	
Z Score	≤ -3 SD	86	2 (2.27)	88	0.000
	≤ -4 SD	36	5 (12.1)	41	
	Severe wasting	110	8 (6.77)	118	

Table 5. Relation of death to selected patients variables.

Causes of death	No. (%)	Duration of hospitalization		Age of patients (months)		
		1-7	>7	1-6 m	6-12 m	12-36
Spesis	9 (60)	7 (58.3)	2 (66.7)	4 (50)	4 (80)	1 (50)
Severe pneumonia	3 (20)	2 (16.7)	1 (33.3)	2 (25)	0	1 (50)
Chronic diarrhea	1 (6.7)	1 (8.3)	0	1 (12.5)	0	0
Complicated malnutrition	2 (13)	2 (16.7)	0	1 (12.5)	1	0
Total	15 (100)	12 (100)	3 (100)	8 (100)	5 (100)	2 (100)

Table 6. Causes of death in relation to days of hospitalization and age of patients, p-value is not significant (Exact FissureTest).

(0.008, 0.000) respectively. The mortality in NRC was 5.68% and sepsis constitutes 60% of all deaths and 58.3% of death cases due to sepsis in first 7 days of admission (7 out of 9), as well as 80% of all death cases occur in 1-7 days. Death in infants less than 6 months accounts for about 53% but neither the age nor the duration of hospitalization significantly associated with the causes of death, (Table 6).

DISCUSSION

Approximately half of all deaths in children under five are due to under-nutrition as well as they are at risk of death from common infections.[4] The problems of malnutrition in Iraq began to appear from the early nineties, due to the circumstances the country had been through due to war, sanctions and many other factors, which collectively led to many health problems, one of which was malnutrition. Management of SAM according to WHO guideline in nutrition rehabilitation ward was established actively since 2003 in Basra General Hospital.

In 2011 "Multiple indicator cluster survey" (MICS4) was carried; shows that 8% of under-five children in Iraq are moderately or severely underweight, and 4% of them are severely underweight. Additionally, more than one fifth (22%) of children are severely or moderately stunted with 10% of them severely stunted, results also indicate that almost 7% of children are wasted, and 3% of them are severely wasted.[5]

Current study shows that the admitted malnourished children ages are below 36 months and 2/3 of them below twelve months similar result concluded by Firas et al in Basra who shows that more than 2/3 of admitted children to NRC were below 12 months age, and female affected more than male, this is in agreement with other survey possibly because of much care given for males than females.[6] In contrast to a study carried out by Manisha et al in India, their studied patients aged 6-59 months.[7]

Pneumonia reported with higher frequency in admitted children with malnutrition due to impaired immunity;

followed by acute diarrhea and chronic diarrhea; which is due to starvation diarrhea, and decreased pancreatic enzymes secretion. Similar finding was concluded by Esi et al. in Ghana[8] and Ashraf et al in Dhaka.[9]

All admitted children are severely malnourished according to the admission criteria postulated by WHO guide line for management of severe malnutrition; those below 6 months are with severe wasting having problems with breast feeding. Only 6.7% of patients present with edema; this is in agreements with study carried out by Khanam et al;[10] and Ashraf et al in Bangladesh.[9] Whom conclude; that marasmus was predominant in Asian countries while kwashiorkor in Africa.

Although the duration of management of severe malnutrition according to WHO manual of management of SAM; is about six weeks, it was noted that higher frequency of children admitted to the nutrition rehabilitation ward for 1-7 days and maximum stay at hospital was 30 days (only in 5 patients), as well as they were discharged home on their request for personal and social reasons, many studies had same conclusion.[7,11]

More than two third of patients had moderate-good weight gain, many literatures with different results; mean weight gain is 9.7 and 5.5 g/kg/day in study carried out by Gaboulaud et al[12] and Mitulkumar et al[11] respectively.

With proper case management of severe malnutrition the case fatality rate reduced to less than 5%. In current study the mortality was 5.68% which is close to the desired target. Over previous years 2008, 2009, 2010 and 2014; the mortality in NRC of Basra General Hospital decreases from 7.6%, 7%, and 6.9% to 5.6% respectively from registered data. Other researchers Hossain et al record a case fatality rate of 10.8%.[13]

Indicators for monitoring therapeutic effect of industrial and locally prepared therapeutic milk in term of recovery (weight gain), mortality and duration of hospitalization show no significant differences.

This is in agreement to the results concluded by Ould Sidi et al whom investigate the therapeutic effectiveness of locally prepared F75 and F100 for treatment of severe malnutrition in Mauritania.[14]

CONCLUSIONS

We conclude that industrially produced therapeutic milk shows no superior advantage than locally prepared milk in term of weight gain, mortality and days of hospitalization in the management of severe acute malnutrition.

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