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A Review of the literature on the use of oral lipids as a caloric supplement

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A REVIEW OF THE LITERATURE ON THE USE OF ORAL
LIPIDS AS A CALORIC SUPPLEMENT

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1. Introduction

Clinicians have long known the need for caloric supplementation. Anorexia leading to weight loss and negative nitrogen balance is a common symptom of illness. Chronic malnutrition contributes to fatigueability, weakness, irritability, as well as the most important factor, further anorexia. Disease states that are accompanied by hypermetabolism such as febrile illnesses and many malignancies, exaggerate and magnify these effects.

To combat these effects of anorexia, protein and carbohydrate caloric supplements have been extensively investigated, and used successfully in the human subject. However an excessively large bulk is necessary to administer adequate calories.

The effective use of an oral lipid preparation has opened a new field of caloric supplementation. Fat, with nine calories per gram contains approximately two and one quarter times the calories per gram produced by carbohydrate or protein.

Although fat by its tremendous caloric value overcomes the problem of bulk, this foodstuff has serious objections which had to be surmounted. Among these are palatability, stability and absorbability.

These problems were dealt with as will be described.

As an illustration of the value of a lipid preparation, let us take a hypothetical case in which we assume that all of the preparations administered are completely utilized. At bedrest the average patient requires 1600-1800 calories per day to maintain body weight. To regain lost weight diets up to 3000 calories are not unusual. Because protein and carbohydrate are calorically identical (four calories per gram) the following will illustrate for both:

Using a twenty per cent (20%) solution intravenously supplying twenty grams per 100 cc or eighty calories per 100 cc, the patient would require two liters to maintain body weight at bedrest. As much as four liters would be required to provide 3000 calories.

Contrast the above with a lipid preparation containing four calories per cc, which is the preparation we will deal with in this paper. Seven ounces (210 cc) of this emulsion provides eight hundred forty calories. In this hypothetical case one liter of protein or carbohydrate was required for the same number of calories.

A similar comparison of caloric supplements can be made in dealing with patients with various illnesses, including intestinal obstruction and progressive ill-

nesses, such as tuberculosis as will be seen on the following pages.

II. FAT METABOLISM (in brief)

(a) Source

While many of the fatty acids are synthesized by the body a few are not (unsaturated fatty acids), and are therefore spoken of as essential components of the diet. These fatty acids are linoleic (with two double bonds), linolenic (with three double bounds), and arachidonic (with four double bonds) (1).

(b) Digestion

The two main theories of fat absorption are those of Verzar and McDougall (2) and of Frazer and co-workers (3). They differ mainly in the degree to which lipolysis is said to occur in the intestinal lumen and in the fate of lipolysis.

Verzars theory is one of complete hydrolysis of triglycerides to fatty acids and glycerol, and direct absorption of the fatty acids produced.

Frazer's partition theory differs from the above in the following respects:

(1) Partial hydrolysis of triglycerides producing mono- and diglycerides plus free fatty acids

and glycerol.

(2) Simultaneous emulsification of the rest of the triglycerides by means of a system comprised of fatty acids, mono- and diglycerides and bile salts.

Sager (4) performed experiments to show that mono- and diglycerides which arise in the breakdown of fat by their great surface activity promote emulsification and subsequent absorption of fat.

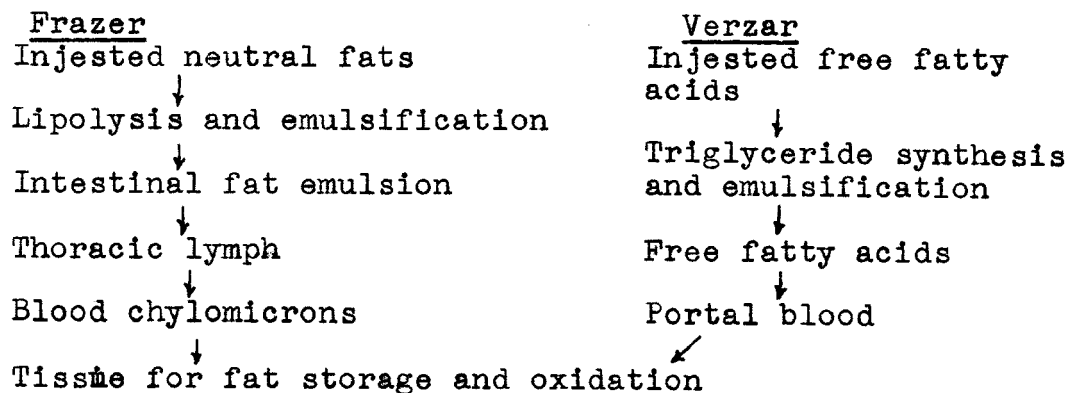
(c) Absorption

(1) Emulsified triglycerides are taken up by lacteals and lymphatics to the thoracic duct.

(2) Free fatty acids go directly to the portal blood.

The two theories are probably least divergent when dealing with fats with short fatty acid chains. As such they probably undergo emulsification and complete hydrolysis.

With long chained fatty acids, the following will illustrate the chief variances between the two theories:



Although the theories vary in the process of absorption both agree that the fat is acted upon by a weak gastric lipase and strong lipolytic enzymes of the pancreas and small intestine. Bile functions to promote absorption in the following ways:

(1) Bile salts decrease surface tension and thereby aid in emulsification by decreasing particle size.

(2) Bile salts activate pancreatic enzymes.

In 1924 it was noted that the blood of man and animals when viewed with a dark field microscope contained numerous particles with Brownian movement. These particles were given the name Chylomicrons (5). Average diameter of chylomicrons was 0.5 microns, and stains indicated their composition to be of neutral fat. Smaller particles, lipomicrons (6), were also noted. Chylomicrons can be counted with a fair degree of accuracy and therefore are a definite aid in determining mode of fat absorption, transportation and disposition. Fatty acids in the process of absorption are converted to neutral fats, chylomicrons are neutral fats with a stabilizing surface film.

Following meals a definite rise in chylomicrons was noted. The particles can be counted and placed on a graphic curve. Tests (7) indicated that this curve remains relatively constant in the same individual.

Prolonged curves were noted in the aged (6).

In general, fats are highly digestible. Fats with short chains and low melting points absorbability as high as ninety seven per cent were noted. Mutton fat, with a melting point of fifty degrees Centigrade is eighty eight per cent digestible.

111. FUNCTIONS OF FAT IN THE DIET.

Fat is found in all tissues of the body except the brain, and comprises ten to twelve per cent of the body weight. It is also the chief total energy store.

There is no nutritional requirement for fats or carbohydrate corresponding to that for amino acids. The normal person fares equally well on a diet relatively high or low in fat or carbohydrate. Normal caloric requirements can be met by varying proportions of these foodstuffs. However, as has been pointed out, a few of the fatty acids are essential in the diet. Food oils, egg yolk and animal organs and tissue provide an adequate intake of the fatty acids in the average diet. Fats serve as the greatest source per gram of calories; this is of prime importance where energy supply is a critical factor.

Fats act to spare protein. However, Deuel (8) theorized that carbohydrate and not fat acts to spare

protein in nitrogen starvation. In support of Deuel, Rasmara (9) working with parenteral nutrition found "a nitrogen sparing action is exerted by carbohydrate and not fat".

While carbohydrate spares protein in many ways, fat spares protein by virtue of its caloric properties. This occurs only after necessary carbohydrate has been supplied (9). One hundred grams of glucose per day will cover the average adult need. This one hundred grams enables the body to meet energy requirements without gluconeogenesis from tissue protein. Based on experiments the normal adult on the fourth day of starvation excretes about 15.0 grams of nitrogen in the urine. A protein poor but calorically adequate diet reduced this to 5.0 grams per day. Elman (19) calculated that 62.5 grams of protein were broken down for energy, the rest of the energy was derived from tissue fat.

Experiments were performed (10) in which fat replaced carbohydrate (equicaloric) in patients with nitrogen equilibrium, and an adequate diet. In three days a negative nitrogen balance was noted.

Fat may have operative functions for which carbohydrate will not suffice (11). It has a definite

relationship to the physical capacity of the individual. Experiments on rats (12) on a diet of 0-40% fat showed a definite increase in physical capacity, increasing in direct proportion to the increase of fat in the diet. This was measured by the rats ability to swim in water with weights attached to them. Swift (13) found that fat in the diet confers "economy of utilization of food energy".

Fat favors more efficient protein utilization by delaying gastric emptying time (14). Other functions, such as heat regulation, protection etc., are well known.

IV. EFFECT OF EMULSIFYING AGENTS ON LIPID ABSORPTION

Studies (15) in which fasting rats were given by mouth 0.45 ml of maize oil with 1.5 ml of six per cent soya bean phosphatide or Tween 80 were performed. Control rats were given maize oil only. The animals were sacrificed in four hours and the fat remaining in the intestine estimated. About seventy per cent of the fat was absorbed in both groups, revealing little if any effect by emulsifying agents.

Shoshkes (15) et al studied the effects of intestinal ligation below the pancreas and at the ileo-cecal junction. Maize oil with or without emulsifying agents was then

introduced into the intestinal lumen by a small incision. The animals were sacrificed at four hours and analysis of the intestinal contents revealed twenty per cent absorption, with no effect of emulsifying agents noted. Other investigators found that these agents did inhibit fat absorption (17).

Utilizing similar techniques to the above, no effect on fat absorption by emulsifying agents was further substantiated (18). This work also pointed out that fat emulsions were more rapidly absorbed in direct relation to their decreasing particle size. The fact that there was no absorption of unemulsified paraffin is evidence for the purely mechanical nature of the process.

V. PROCEDURES TESTING THE STABILITY OF LIPOMUL*

Lipomul (oral) is a fat emulsion containing forty per cent by weight peanut oil, ten per cent sucrose, two per cent soya bean phosphatide, and 0.2% synthetic emulsifier (alkylaryl polyether alcohol).

In the emulsification of this product, it is claimed that homogenization is so complete that particles having an average diameter of one micron are produced. By comparison cream particles have a diameter of five to twenty microns. Lipomul yields four calories per cc.

*Lipomul (oral) is the trade name of this product produced by The Upjohn Company.

The stability of this product in the gastrointestinal tract has been studied as presented by the Upjohn Co. (20). Three hundred cc of artificial gastric juice was added to sixty cc of Lipomul. Pepsin was added and the pH adjusted to approximate the height of gastric digestion. The solution was maintained at forty degrees Centigrade for three hours, and this resulted in no breakdown of the emulsion. This indicates that the emulsion reaches the intestine intact. This result was not obtained with cream under the same conditions where microscopic agglomeration was noted.

Mixtures of two ounces of Lipomul per three hundred cc of gastric fluid and of two ounces of cream per three hundred cc were set up. Both mixtures were left at room temperature for three hours, while identical mixtures were heated at forty degrees Centigrade for three hours. Microscopic examination prior to the studies showed uniform particle dispersion in all solutions. The results obtained were as follows:

1. Cream

- (a) $1\frac{1}{2}$ hours at 40 degrees showed marked breakdown with oily layer at the surface.

- (b) $2\frac{1}{2}$ hours at room temperature showed oily separation with oily layer at the surface.

2. Lipomul

- (a) $1\frac{1}{2}$ hours at 40 degrees ... little change
- (b) $2\frac{1}{2}$ hours at room temperature .. no change
- (c) 3 hours at room temperature ... little gross change
- (d) 3 hours at 40 degrees ... little gross change, microscopic examination from the surface revealed a few particles 4-40 microns in size.

VI. THE USE OF AN ORAL LIPID IN HEALTHY ADULTS

Thirty three healthy adults (21) were given initial doses of 125-250 ml of Lipomul between the evening meal and bedtime to assure maximum digestion and little interference with the appetite. Twenty five tolerated this dosage well, and weight gains from one to eleven and one-half pounds were noted. The group average weight gain equalled the average amount of extra fat injected over the five to fifty three day study period. Average weight gain was one-tenth pound for each one-tenth pound of fat (110 ml of the emulsion).

VII. THE USE OF AN ORAL LIPID IN DEALING WITH THE ILL

Ninety eight patients in need of calories were selected (21), and a dosage of 65-250 ml per day by mouth was tolerated well by seventy three. The study was continued over periods of 5-150 days, and weight gains of one to twenty pounds were noted. The average

weight gain equalled 0.2 pound for each 0.1 pound of fat injected.

Fifty two patients derived a favorable caloric balance as shown by weight gain. The weight of most of these patients was static or decreasing prior to the study. Increased appetite, increased strength and a feeling of well being was also noted in this group.

Approximately twenty five per cent of both healthy and ill groups showed intolerance as manifested by nausea, vomiting, constipation or diarrhea. Lower original doses and more gradual increase might have minimized this intolerant group.

VIII. EXPERIMENTAL AS WELL AS CLINICAL DEMONSTRATION OF THE USE OF A LIPID AS A PROTEIN SPARER.

It has long been known that the utilization of dietary protein requires the presence in the diet of non-protein energy producing foods (22).

(a) Experimental studies.

Pearson and Panzer (23) found that weanling rats fed a complete diet deficient only in fat gained twenty nine per cent less than rats on a diet containing eight per cent corn oil or lard. The rats receiving adequate fat also showed a diminished fecal and urinary excretion of amino acids. This illustrates the role fat plays

in growth, as well as its protein sparing action. Fat in the diets of rats on a reduced protein diet maintained optimum growth (24).

Nephrectomized dogs and rats were studied to simulate patients in renal failure (25). These animals had a longer survival period on a low salt diet which avoids overload of the circulation, resulting from potassium accumulation and other non-excretable substances. Emulsions of fat in aqueous carbohydrate, free of protein and salt provided the longest survival time for the acute experiments (rats 4.6 days, dogs 6 days). Malnutrition must be combatted in longer experiments where animals are maintained on artificial kidney(26).

Such a diet was devised (27) providing adequate vitamin, mineral and protein (lactalbumin) requirements. The diet contained 2.23 calories per ml. Dogs were given seventy calories per kilogram per day and were also allowed free access to water. The dogs were maintained for thirty to seventy days in good nutrition.

Adequate calories with a minimum supply of protein in the diet kept endogenous protein catabolism at a minimum. Elman (19) supported this conclusion.

(b) Clinical studies

One male volunteer, in good health, was placed on a calorically inadequate diet. It was found that fat

compared favorably with carbohydrate in its nitrogen sparing properties (14). An oral fat supplement produced weight gain and nitrogen retention in the nutritional repletion of a patient with intestinal insufficiency due to resections.

The actual clinical counterpart of the above experimental studies is the patient with acute renal failure. Such patients can be maintained during the period of oliguria and anuria on a protein free, electrolyte free, calorically adequate diet to reduce protein metabolism to a minimum (28). The following diet was devised for such a purpose (29):

- | | |
|----------------|-----------|
| (1) Glucose | 400 grams |
| (2) Peanut oil | 100 grams |
| (3) Water qs | 1 liter |

The diet was given by naso-gastric tube, 2500 calories per day. Water to overcome insensible loss was also given.

More palatable diets were devised (30) and were given by tube and orally. Oral fat emulsions were more effective than intravenous glucose to maintain calories and keep blood urea nitrogen at a minimum in disease states where elevation of blood urea nitrogen and accelerated protein catabolism are noted.

These results were confirmed in patients with normal renal function (21). Three male patients on a 1200 calorie diet consisting of 152 grams of carbohydrate, 40 grams of protein, and 56 grams of fat were noted to loose weight and go into a nitrogen deficit. No strenuous activity was allowed.

Nitrogen determinations done prior to and during the study showed that 250-675 ml of Lipomul daily provided nitrogen equilibrium.

Four volunteers on a low protein diet received 250-550 cc (1000-2200 calories) per day (39). Nitrogen and potassium deficits due to calorically inadequate diets were abolished. Three of the four showed good assimilation of fat. In no instance did the patient make up the deficit between intake and needs by utilizing body fats.

The conclusion was that energy requirements were met by the lipid emulsion and dietary protein was spared to enter into protoplasm.

IX. VALUE OF LIPID IN DIET OF PATIENTS ON STEROID THERAPY.

Six children with rheumatic disease were selected for study (31). An attempt was made to combat the catabolic effects of ACTH and cortisone, namely- sodium, potassium, phosphate and calcium losses by

dietary means. The following diets were used:

	Calories %
Milk protein	15
Lactose U.S.P.	50
Oral fat (Lipomul)	35
Total	<u>100</u>

Mineral supplement:

Calcium potassium lactate grams per day4

Vitamin supplements:

Vitamin C ounces of orange juice per day4

Vitamins A & B ounces of cod liver oil per day ..0.7

Fluid supplement:

Fruit juices and water 1 liter

The diet supplied 2.0 - 3.0 grams of protein per kilogram per day. Studies of the blood and urine revealed that the synthetic diet maintained electrolyte balance within normal limits throughout the period of steroid therapy.

Patients on a free selection diet during periods of low or negative nitrogen retention showed marked elevation of blood amino acids and excessive loss of amino acids in the urine. This change was not noted in the group on the synthetic diet. These studies seem to indicate the need for fat for its caloric action in the diet.

X. USE OF LIPOMUL BY MOUTH, GASTROSTOMY OR JEJUNOSTOMY

Seven patients were selected, five with gastric

tubes, one with gastrostomy and one with jejunostomy (21). Lipomul alone was not tolerated, but was tolerated well with a liquid tube feeding. One of the patients in the thirty days prior to the study lost 5.7 pounds on a diet containing 1000 calories. The addition of 2625 ml of fat emulsion (1050 grams of fat) resulted in a 6.6 pound weight gain over a period of thirteen days. Group average weight gain equalled 0.2 pound for each 0.1 pound of emulsion injected.

Another group was also given a liquid diet as a supplement or complete feeding (32). The feedings included vitamins, minerals, 100 grams protein concentrate and 1000 ml of Lipomul. The results were as follows:

(1) Seventy six patients on a diet including forty per cent fat emulsion.

(2) Four Hundred grams of fat in the upper intestinal tract is tolerated well and absorption is almost complete.

(3) Marked weight gain in patients with benign obstruction of the upper intestinal tract as well as malignancies of the mouth. Beneficial results with malignant obstruction of the upper intestine.

(4) Marked positive nitrogen balance can occur

with moderate protein, high caloric intake.

(5) Nausea and vomiting or constipation in fifty per cent. Usually transitory and did not require cessation of therapy. The patients received 400 grams of fat per day yet the fecal fat increased only about three grams daily.

XI. THE USE OF AN ORAL LIPID IN OTHER DISEASES.

(a) Tuberculosis (32)

Oral fat was given sixty three patients with pulmonary tuberculosis. The pure emulsion produced anorexia and nausea. When homogenized with milk and milk protein it was tolerated well for longer periods. Patients with static disease showed weight gain and in those patients with progressive tuberculosis the expected weight loss was minimized.

(b) Poliomyelitis

Since the patients were primarily children, chocolate flavored Lipomul was utilized to provide palatability, as well as calories to prevent protein catabolism. The protein fed was thereby utilized by the body for tissue and antibody formation. The fat also provided heat and energy with little demand on the digestive system.

(c) Peptic ulcer

Five patients (21) were observed to gain weight and noted partial relief of symptoms.

(d) Pancreatic fibrosis (21)

One patient - no effect with Lipomul alone. This patient was malnourished and had no exocrine pancreatic secretion. Lipomul plus pancreatic extract produced an eleven pound weight gain in three months.

(e) Myasthenia gravis (21)

One patient on Lipomul noted increased strength and appetite plus a ten pound weight gain in two months. The patient was able to work part time after the two month period.

(f) Hemorrhage after spontaneous abortion (21).

An underweight forty two year old female received 125 ml Lipomul per day for five months and gained twenty two pounds.

(g) Cirrhosis, hemiplegia and rheumatoid arthritis (35).

Thirty five chronically ill patients were selected. Four cirrhotics and thirty one with arthritis or hemiplegia (normal liver function). Uniform diet for all one week before and during the period of supplementation.

Carbohydrate	300 grams
Fat	100 grams
Protein	100 grams

This diet supplied 2500 calories daily. After the above diet was taken for one week, 240 cc of Lipomul was added. Results were:

- (1) 240 cc tolerated well and is an adequate supplement.
- (2) This dosage did not produce a decrease in appetite.
- (3) BSP fluctuations noted in both groups did not accurately represent hepatic excretory function.

Normal fat content in the diet is recommended in liver disease (36 and 37) for maximum therapeutic response. This finding is disputable however the above investigators found that the above plus adequate carbohydrate, protein, and B complex vitamins are needed to alleviate impaired liver function.

XII. CONTRAINDICATIONS TO THE USE OF FATS IN THE DIET

The injection of fat produces the following effects (38):

Fat $\begin{matrix} \longrightarrow & \text{Cholecystekinin} & \longrightarrow & \text{Gall Bladder contraction} \\ & \searrow & & \\ & \text{Enterogasterone} & \longrightarrow & \text{Diminished gastric} \\ & & & \text{secretion and motility.} \end{matrix}$

Therefore, the presence of biliary calculi is an absolute contraindication. Also from the above, it can be seen that the use of fat in patients with intestinal obstruction is done with caution.

The occurrence of definite fat intolerance in patients has been pointed out. It seems likely that

the lipid preparation when given in combination with other liquids, and in small original doses 125-250 ml, that evidence of intolerance would be noted in a smaller percentage.

The only absolute contraindication noted thus far in the investigation is the presence of biliary calculi. The use of fat in hyperlipemic states has been extensively investigated, however it is not within the scope of this paper. It is unlikely that lipid emulsions would have any effect because of the short duration of their use. Opinion, however should be deferred pending further study.

XIII. OVERDOSAGE OF LIPOMUL

In general the greater the dosage of Lipomul the higher percentage of intolerance. Gastro-intestinal disturbances are the only manifestations of overdose.

The greatest amount taken in one day was 1250 ml (500 grams of fat) due to an error (21). This amount was given in divided doses and resulted in diarrhea of one day duration, and a transient decrease of blood carbon dioxide from 21.6 meq to 14.5 meq. These were the only effects noted in this patient, after receiving this tremendous amount of fat in one day.

XIV. SUMMARY

The need for calories in the underweight patient has long been a problem in clinical medicine. In order to supply the greatest number of calories in the smallest volume fats with a caloric value of nine per gram are the best energy source of foodstuffs. Fat produces $2\frac{1}{4}$ times the number of calories per gram produced by carbohydrate or protein.

To provide an effective oral lipid caloric supplement the problems of palatability, stability and absorbability of a concentrated lipid preparation had to be dealt with and overcome. Toward this end the product Lipomul has been made available. This preparation contains 40% by weight peanut oil, 10% sucrose and 2% soya bean phosphatide and 0.2% synthetic emulsifier. Peanut oil contains 20-25% linoleic acid and is therefore a good source of one of the essential unsaturated fatty acids which the body is unable to synthesize.

Lipomul is prepared by a process of homogenization in which a uniform dispersion of particles having an average diameter of one micron are produced. This is important as it has been noted that the absorbability and palatability of lipid emulsions increase in direct relation to decreasing particle size.

These investigators determined that emulsifying agents had little or no effect on lipid absorption.

Under conditions approximating the height of gastric digestion Lipomul was more stable than cream. This assures that most of the preparation will reach the intestine intact. Most of the preparation is utilized as shown in the group of patients given 400 grams of fat daily, the fecal fat showed an average daily increase of 3 grams.

The essential fatty acids are linoleic, linolenic, and arachidonic and are adequately supplied in the average diet.

Fat functions to spare protein by its caloric value alone. This occurs after necessary carbohydrate (100 grams daily in the adult) has been supplied in the diet. Fat in the diet increases the physical capacity of the individual as well as aiding in protection, heat regulation and serving as the bodies chief energy store.

Thirty three underweight but healthy adults were given Lipomul. Twenty five tolerated a daily dosage of 125-250 ml. The average weight gain was 0.1 pound for each 0.1 pound of extra fat injected.

Ninety eight patients with a variety of illnesses were selected in a second group. Seventy three tolerated a daily dosage of 65-250 ml of emulsion and gained (group average) 0.2 pounds for each 0.1 pound of emulsion injected.

Approximately 25% of the above patients demonstrated intolerance, manifested by nausea, vomiting, diarrhea or constipation. One half of this group were intolerant to fat in general.

Studies were also performed which show that fat in the diet spares protein by providing necessary calories, and thereby allowing protein to enter into tissue formation. Oral lipids were used effectively in disease states where elevation of blood urea nitrogen makes it desirable to keep endogenous protein catabolism at a minimum.

An attempt to combat the catabolic effects of ACTH and cortisone was made. The conclusion of these studies was that patients on steroid therapy should receive a fat supplement for its protein sparing and caloric value.

Seventy six patients were given Lipomul by mouth, gastrostomy or jejunostomy as a partial or complete feeding. In general 400 grams of fat in the intestine

was tolerated well and weight gains were noted. It was also noted that positive nitrogen balance can occur with moderate protein, high caloric intake.

Patients with tuberculosis were studied and it was found that a lipid supplement produced weight gain or minimized expected weight loss.

Normal fat content in the diet is recommended in liver disease, as shown in patients with cirrhosis or infectious hepatitis. The above in conjunction with high protein, carbohydrate and B complex vitamins produces a maximum therapeutic response.

The only absolute contra-indication to the use of a lipid supplement is biliary calculi. It should be pointed out that the use of fats in patients with intestinal obstruction should be done with caution. As noted above some individuals are intolerant to fat in general and this at present is also a contraindication.

Overdosage does not seem to be a problem. One patient received 1250 ml of Lipomul (550 grams of fat) in one day due to an error. The effect of this error was transitory diarrhea.

The role of fats in hyperlipemic states has not been discussed, and is not within the realm of this paper. However as lipid supplements are used for short

periods only they should have little effect in these disease states.

XV. ACKNOWLEDGEMENT

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XVI. CONCLUSION

The value of lipids as a source of calories is undisputed. Toward this end a palatable lipid emulsion could be very valuable. Although palatability of the emulsion (Lipomul) was increased by decreasing particle size and the addition of flavoring, the fact remains that the emulsion is very rich. The results pointed out in this paper were obtained on a hospital regime, and as such appear promising. As yet the use of a lipid emulsion on an out patient basis awaits further study to provide a still more palatable preparation.

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