

SUMMARY

PROTEIN-SPARING MODIFIED FAST DIET: EFFICACY, SAFETY AND CLINICAL USE — LITERATURE REVIEW

Obesity, defined internationally as a BMI ≥ 30 kg/m², is considered a major public health problem by the World Health Organization (WHO) because of its steady and rapid rise in prevalence in many countries. Québec is not spared from this phenomenon: according to data from the Canadian Community Health Survey – Nutrition, conducted with a representative sample of the adult population aged between 18 and 74 years, the prevalence of obesity was 21.4% in 2004.

A protein-sparing modified fast (PSMF) is generally defined as a very-low-calorie diet (VLCD) with an energy intake less or no greater than 3350 kJ (800 kcal) per day. The goal is to induce rapid and significant weight loss in people with large body fat reserves, while maintaining most of their lean body mass. This diet is widely available in Québec to anyone seeking intentional weight loss, through commercial manufacturers and in medical clinics. However, it is a topic of debate within the specialized scientific community itself.

The Direction générale de santé publique, under the Ministère de la Santé et des Services sociaux, wondering about the practices of physicians who recommend PSMF diets to their patients, asked AETMIS to provide it with scientific evidence on this nutrition therapy. This report is a literature review on the topic.

Methodology

Several search strategies used in Medline, Cochrane Library, Dissertation & Theses and Web of Science helped identify systematic and narrative literature reviews, randomized controlled trials and observational studies. A Web search located expert recommendations and position statements on the PSMF diet and also on the medical management of overweight. Aspects specifically targeted were the conduct and pathophysiology of the PSMF diet, its indications, safety, efficacy in terms of weight loss and impact on overweight-related risk factors,

psychological aspects and the costs it incurs or saves, along with issues affecting care organization and the involvement of professionals in such care.

Nutritional, dietary and pathophysiological aspects

A PSMF diet generally consists of three to four successive stages: a non-systematic preparatory stage consisting of a balanced, moderately low-calorie diet; the protein-fasting period itself; a refeeding stage involving dietary diversification characterized by a gradual increase in energy intake through the reintroduction of carbohydrates; and finally, a long-term weight stabilization and maintenance phase.

The energy intake of the diet chiefly consists in an adequate intake of protein of high biologic value to prevent the risks of protein-energy malnutrition linked to a negative nitrogen balance. The PSMF diet is based on conventional foods or specially formulated products. Optimal intakes of lipids, carbohydrates, fibre and micronutrients are still under discussion.

Expert consensus exists on the need to combine the PSMF diet with a patient support plan that includes physical activity, eating behaviour modification and psychological support.

The effects of this diet on changes in body composition are not yet fully known. While it induces body fat loss, initially visceral fat, it also leads to loss of lean body mass, electrolytes and minerals. It causes neuro-hormonal changes and modifies energy expenditure, although this is still not fully understood.

The duration of the protein-sparing stage per se varies according to the study but is most often between 8 and 16 weeks. However, the literature does not allow us to definitively establish the optimal amount of time that this stage should last. The attrition rate is also far from negligible, ranging from 14.6% to 65.0%, depending on the study.

Indications and contraindications

There is no consensus among experts and clinicians on the use of PSMF diets. Some advise against prescribing it to patients with obesity; others reserve it for limited indications, while issuing a series of necessary precautions. The PSMF diet is not indicated for motivated individuals who are not overweight. It would therefore concern adults who are younger than 60–65 years, who face serious health risks owing to their excess weight and who have failed in previous weight-loss efforts on well-managed and balanced moderately low-calorie diets. There is no evidence on the basis of which it is possible to define the upper and lower BMI thresholds or BMI range that would serve as a reference for proposing this form of nutrition therapy. Nevertheless, there seems to be little room for this type of diet in people with a BMI < 30 kg/m², except for those with a BMI between 27 and 30 kg/m² who have failed to lose weight on previous well-managed, conventional diets, who face overweight-related medical complications causing a serious health risk and who therefore need to begin losing weight quickly.

Contraindications exist and mostly relate to catabolic, cardiovascular, psychiatric, hepatic vascular, renal and metabolic disorders and to particular situations such as pregnancy, breastfeeding and age. Some precautions must also be taken, such as adjusting patients' medication dosages.

Safety and tolerance

Cardiac deaths occurred in the 1970s with this type of diet; however, the causes were not determined with absolute certainty. To date, some adverse effects have been reported, especially gallstones and cardiac or psychiatric disturbances. Mild side effects are more common, however, and these require adjustments without cessation of the diet.

Study outcomes do not agree on the safety of the PSMF diet in pre-operative situations.

Efficacy outcomes

Short-term weight loss is rapid and significant, greater than that of a conventional diet, that is, a balanced, moderately low-calorie diet. Thereafter, weight regain is frequent, and there is currently no

evidence to suggest that its long-term efficacy is greater than that of a conventional balanced diet.

Concerning its associated risk factors, short-term improvements have been noted in obstructive sleep apnea, glycemic control and cardiovascular problems. Long-term data are less precise.

Psychological aspects

The studies do not conclusively document the positive or negative effects of this diet on patients' mood and potential eating behaviour problems.

Cost analyses

The few analyses available do not inform either on the cost of the PSMF diet or on the economic benefits that it could potentially generate.

Organizational aspects and professional involvement

The PSMF diet requires a multidisciplinary approach and medical supervision. The Canadian legislator has included medical supervision in the Food and Drug Regulations in the section *Foods Represented for Use in Very Low Energy Diets*. The place of physicians and of the different healthcare professionals concerned in such supervision and the linkage between the different practitioners are not clearly described in the literature. Experts propose different approaches: strict medical supervision by a physician before and throughout the diet is advocated by U.S. experts, while surveillance based instead on practitioners' clinical judgment with nurses and dietitians actively participating in the medical support plan is advocated by Finnish and Swedish authors.

Conclusions

On the basis of studies of fair or poor quality, several having low levels of evidence, AETMIS concludes the following:

- The PSMF diet is in no way indicated for people who are not overweight.
- In cases where people are required to lose weight, the leading recommendation by nutrition experts is to prescribe a personalized, balanced moderately low-calorie diet with an energy deficit ranging from 500 to 1000 kcal/d.

- Experts are divided on the place of the PSMF diet as a therapeutic option for obesity. Some believe that the PSMF diet has no place in the current range of dietary interventions. Others, in official position statements, do not exclude its use and consider that it may be used for **limited indications**, especially in the management of people with obesity (BMI ≥ 30 kg/m²) or people with a BMI between 27 and 30 kg/m² who have failed to lose weight on previous well-managed, conventional diets, who face overweight-related medical complications causing a serious health risk and who therefore need to begin losing weight quickly.
 - Examination of the scientific evidence provided in studies on PSMF diets in clinical settings reveals the following:
 - **Compliance** with this diet is difficult and attrition rates are high.
 - **Short-term weight loss** is rapid and significant and is accompanied by also short-term changes in clinical and biological parameters suggesting improvements in some associated risks.
 - Its **long-term efficacy** for weight loss remains less certain, given the conflicting outcomes of the two meta-analyses evaluating this aspect.
 - In addition, no evidence was found to conclude on the benefit of **repeated courses** of PSMF.
 - The **adverse effects and complications** observed require medical supervision during the fasting stage.
 - The **potential costs and savings** generated by PSMF diets, of which little is currently known, should be subjected to in-depth study.
 - Given the lack of long-term efficacy of this diet for real weight loss and its reported dangers, compared with conventional weight-reduction diets, and given the need for medical monitoring, although little documented, combined with a multidisciplinary intervention involving other health professionals, the principle of medical precaution (*primum non nocere*) is warranted, while that of refraining from the use of this diet must be considered.
 - When used, the PSMF diet should be an integral part of the patient's **general support program** conducted by a multidisciplinary team and including physical activity, support for changing eating behaviour, potential psychological follow-up, etc., as in the case of a balanced moderately low-calorie diet.
- The extent and nature of health **professional involvement** in this process have not been fully elucidated. The existence of possible adverse effects from PSMF diets demonstrates the importance, in terms of safety, of ensuring that this diet is prescribed by a qualified physician and monitored by health professionals. Given all of these elements, it would be important to draw up a profile of the use of this type of diet in Québec with its achieved outcomes.
- Reflection on the place of this nutrition therapy could be part of a general reflection on the management of obesity, which would include all concerned parties. Lastly, the place of the different professional practitioners in conducting diets geared toward intentional weight loss, including PSMF, will remain difficult to recognize so long as there is reluctance to acknowledge that obesity is a complex chronic disorder requiring consideration of its biological, social and psychological dimensions.