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A Consensus Report on Management of Type 2 Diabetes Mellitus in Iran

Alireza Esteghamati[1], Mojtaba Malek[2], Farhad Hosseinpanah Ghasabeh[3], Farzad Hadaegh[4], Mohammad Afkhami-Ardekani[5], Hamid Reza Aghai Meybodi[6], Mohammad Hossein Dabbaghmanesh[7], Fatemeh Ghaemi[8], Seyed Adel Jahed[9], Saeed Kalbasi[10], Mojtaba Mehrdad[11], Zohreh Mousavi[12], Mitra Niafar[13], Hassan Rezvanian[14], Mojgan Sanjari[15], Amir Ziaee[16], Mohammad E. Khamseh[17]*

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Abstract

Background: Type 2 diabetes mellitus (T2DM) is one of the most serious public health problems all over the world. Development of local consensus on management of T2DM, providing clinicians, researchers, and policymakers with updated and valid evidence in consideration of practical issues, is crucial. Therefore, we aimed to develop a consensus report on management of T2DM in Iran.

Methods: A task force group comprised of experts in diabetes management reviewed published literature. The task force members reached the majority agreement on all recommendations after participating in several group meeting discussions.

Results: The consensus provided recommendations on diverse aspects on management of people with T2DM in Iran. The recommendations covered the following topics: first-line treatment, diabetes management in people with obesity, combination therapy in people with T2DM, injectable therapy, and non-alcoholic fatty liver in people with T2DM.

Conclusion: Considering evidence-based guidelines, the task force group developed a consensus to address important clinical issues in the management of people with T2DM in Iran.

Keywords: Iran, Diabetes Management, Consensus, Consensus report, Type 2 Diabetes Mellitus (T2DM)

Conflicts of Interest: Abidi Pharmaceuticals sponsored group meetings and logistic arrangements. However, the company did not have any role in scientific discussions and development of the consensus recommendations.
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Corresponding author: *Dr Mohammad E. Khamseh, khamseh.m@iums.ac.ir*

1. Endocrinology and Metabolism Research Center (EMRC), Vali-Asr Hospital, Tehran University of Medical Sciences, Tehran, Iran
2. Research Center for Prevention of Cardiovascular Disease, Institute of Endocrinology and Metabolism, Iran University of Medical Sciences, Tehran, Iran
3. Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran
4. Prevention of Metabolic Disorders Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran
5. Diabetes Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran
6. Evidence-based Medicine Research Center, Endocrinology and Metabolism Clinical Research Institute, Tehran University of Medical Sciences, Tehran, Iran
7. Endocrinology and Metabolism Research Center, Shiraz University of Medical Sciences, Shiraz, Iran
8. Department of Transplantation & Disease Management, Vice Curative, Ministry of Health and Medical Education (MOHME), Tehran, Iran
9. Gabric Diabetes Education Association, Tehran, Iran
10. Department of Endocrinology and Metabolism, School of Medicine, Loghman Hakim Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran
11. Department of Endocrinology, Guilan University of Medical Sciences, Rasht, Iran
12. Metabolic Syndrome Research Center, Mashhad University of Medical Sciences, Mashhad, Iran
13. Endocrine Research Center, Tabriz University of Medical Sciences, Tabriz, Iran
14. Isfahan Endocrine and Metabolism Research Center, Isfahan University of Medical Sciences, Isfahan, Iran
15. Endocrinology and Metabolism Research Center, Institute of Basic and Clinical Physiology Sciences, Kerman University of Medical Sciences, Kerman, Iran
16. Rasool Akram Medical Complex, School of Medicine, Iran University of Medical Sciences, Tehran, Iran
17. Endocrine Research Center, Institute of Endocrinology and Metabolism, Iran University of Medical Sciences, Tehran, Iran

↑What is "already known" in this topic:
Type 2 diabetes mellitus (T2DM) is a chronic disease that imposes significant physical, economic, and psychological burdens. Various guidelines exist worldwide in relation to the diagnosis and management of T2DM. Physicians need to follow evidence-based recommendations to improve health-related outcomes.

→What this article adds:
Taking into account global recommendations, local economic/social circumstances, cost of treatment, insurance coverage, and medication availability, the task force developed a consensus report to highlight practical recommendations for the management of T2DM in Iran.

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Introduction

Diabetes mellitus is the fourth most prevalent noncommunicable disease globally. It kills 6.7-million people each year across the world and is one of the most serious public health challenges all over the world (1). In 2021, approximately 537 million adults (20–79 years) were living with diabetes.

The total number of people living with diabetes is predicted to soar to 643 million by 2030 and 783 million by 2045 (1). There are more than 73 million people with diabetes in the Middle East and North Africa (MENA); this figure is expected to double by 2040 (2). According to the latest International Diabetes Federation (IDF), type 2 diabetes mellitus (T2DM) is the most common type of diabetes, making up around 90% of all diabetes (3). Iran, as one of the countries of the MENA region, has been affected by the diabetes epidemic (1). The prevalence of diabetes in Iranian adults were reported to be 14% - 15.1% (4, 5).

T2DM management includes lifestyle interventions (diet, exercise), and pharmacological treatment (oral antidiabetic (OADs), injectable therapy). The aims are to achieve glycemic control, prevent or delay the onset of diabetes-related chronic complications, and improve clinical outcomes and quality of life (6).

The field of diabetes care is rapidly evolving with updated clinical evidence. Landmark trials on new OADs are reshaping treatment strategies in parallel with technological progress, facilitating glucose monitoring and improving insulin delivery (7). Meanwhile, the prevalence of metabolic dysfunction-associated steatosis liver disease (MASLD) in people with T2DM is reported to be 55-60% worldwide (8). Diabetes is one of the known contributing factors in the development of MASLD and progression to metabolic dysfunction-associated steatohepatitis (MASH) and advanced fibrosis. Therefore, the possibility of steatotic liver disease should be considered in management plan.

Accordingly, this consensus provides evidence-based practical recommendations to manage T2DM, considering baseline risk stratification. The main focuses are lifestyle interventions, pharmacological treatment, and individualized care to enhance patient-oriented outcomes. This consensus provides healthcare professionals with updated evidence in T2DM management. Moreover, the task force group considered medication availability, cost, and insurance status.

Methods

Evidence acquisition

The task force was comprised of diabetes expert specialists. They reviewed published literature and prepared a consensus on the management of T2DM in Iran. International clinical guidelines were reviewed in detail. Several group meetings were held, and a consensus was reached on all recommendations with a majority agreement.

Definitions

Cardiovascular risk factors were defined as hypertension (Blood pressure ≥130/80 mmHg or receiving antihypertensive treatment), dyslipidemia (non-high-density lipoprotein (non-HDL) cholesterol ≥130 mg/dL), obesity (body mass index (BMI) ≥30 kg/m^2), history of premature cardiovascular disease (CVD) in first degree relatives (Age ≤55 years in men and ≤65 years in women), and current smoking (9-14).

We defined target organ damage at the presence of proven retinopathy, nephropathy, or neuropathy (9-14).

Peripheral artery disease (PAD) was defined as a history of amputation, previous peripheral angioplasty, documented peripheral arterial stenosis, or Ankle-Brachial Index (ABI) <0.9 (9-14).

Established atherosclerotic cardiovascular disease (ASCVD) was considered as a history of acute coronary syndrome (ACS), percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG), Myocardial infarction, Stroke, and peripheral arterial disease (9-14).

ASCVD high-risk individuals included people over 55 years of age with two or more risk factors and adults with at least one documented microvascular complication (nephropathy, retinopathy, or neuropathy) with at least 10-year duration of diabetes (9-14).

We defined chronic kidney disease (CKD) as microalbuminuria (albumin-to-creatinine ratio (ACR) ≥30 mg/g or estimated glomerular filtration rate (eGFR) ≤ 60 ml/min/1.73 m^2, repeated on two separate occasions (9-14).

Excess weight was defined as: overweight: BMI 25–29.9 kg/m^2, obesity class I: BMI 30–34.9 kg/m^2, obesity class II: BMI 35–39.9 kg/m^2, obesity class III: BMI ≥40 kg/m^2 (15, 16).

First line treatment

Question 1: What are lifestyle interventions in management of T2DM?

Recommendations

Lifestyle Interventions

Recommendation 1: To manage diabetes effectively, lifestyle interventions including a healthy balanced diet, 5-7 % weight reduction, 150 min moderate-intensity aerobic exercise per week, and quitting smoking are fundamental. Self-management education provides individuals with sufficient knowledge and skills required to monitor blood glucose more effectively and to make healthy food choices. Collaborative goal-setting and ongoing support are critical to maintaining lifestyle changes. Social determinants of health, including socioeconomic status, access to healthcare, education, cultural issues, housing, job security, and food security, have a great impact on diabetes management. Addressing these issues is crucial to maintaining equality in healthcare. Healthcare providers are encouraged to consider the social context and community resources to overcome barriers and improve health outcomes. For more details, refer to Iranian guidelines for exercise (17-19).

Pharmacological Approaches

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Question 2: What is the first line of treatment in people without established ASCVD, high-risk indicators for ASCVD, heart failure (HF), and CKD?

Recommendation 2: Metformin is recommended as the first line treatment option in people with T2MD and without established ASCVD, high-risk indicators for ASCVD, HF, or CKD (9, 17, 20-23).

Question 3: What is the first line treatment in people with established ASCVD, high-risk indicators for ASCVD, HF, or CKD?

Recommendation 3: For people with established ASCVD and high-risk indicators for ASCVD, sodium-glucose cotransporter two inhibitors (SGLT2i) is recommended as the first-line treatment option. However, glucagon-like peptide-1 receptor agonists (GLP1-RA) with proven CVD benefits are recommended considering patient preference and affordability (9, 10, 21, 22).

Recommendation 4: For people with HF, SGLT2i with proven CVD benefits is recommended as the first choice of treatment (9, 12, 24).

Recommendation 5: For people with CKD and eGFR ≥20 mL/min/1.73 m^2, SGLT2i is recommended as the first choice. In People with an albuminuric pattern of CKD, SGLT2i is recommended, particularly among those with ACR≥200 mg/g. if SGLT2i is not tolerated or contraindicated, GLP1-RA with proven CVD benefit is recommended if it is affordable (9, 11, 21-22).

Recommendation 6: For people with established ASCVD or indicators of high-risk ASCVD, SGLT2i with proven cardiovascular efficacy or GLP1-RA is recommended independent of glycated hemoglobin (HbA1c) and concomitant medications (9, 10, 21, 22).

Recommendation 7: For people with severe hyperglycemia (HbA1c >10%, blood glucose levels ≥300 mg/dL) or those in a catabolic state (severe weight loss), adding basal insulin alone is recommended (9, 17, 21, 23, 25).

Diabetes Management in People with Obesity

Question 4: How to manage excess body weight?

Recommendation 8: Lifestyle intervention is the backbone of an effective weight reduction program. These include dietary calorie restriction, healthy meal plans, physical activity, and behavioral interventions (26).

Recommendation 9: In people with T2DM and with overweight or obese, glucose-lowering medications with proven weight reduction benefits, including GLP1-RA or SGLT2i, are recommended (26).

Recommendation 10: Bariatric surgery might be considered in people with poorly controlled diabetes and with BMI of 30-34.9 kg/m^2. Surgery is strongly recommended if BMI is ≥35 kg/m^2 (26).

Combination Therapy in People with T2DM

Question 5: Why and When combination therapy is indicated in the management of T2DM?

Recommendation 11: Initial combination therapy increases patient adherence and extends time to treatment failure (9, 17, 21, 22, 27).

Recommendation 12: If HbA1c is 1.5% above the target, early combination therapy should be considered from the start (9, 17, 21, 22, 27).

Recommendation 13: If combination therapy is indicated, fixed-dose combination (FDC) (dual or triple therapy) should be considered to improve patient adherence (9, 17, 21, 22, 27).

Recommendation 14: In people who do not reach the glycemic target on metformin monotherapy, metformin should be continued in combination with other indicated medications (9, 17, 21, 22, 27).

Recommendation 15: For people with established ASCVD or high-risk indicators of ASCVD with HbA1c 1.5% above the target, a fixed dose combination of SGLT2i and metformin or adding GLP1-RA to metformin is recommended as the first-line option (27).

Recommendation 16: For people with established ASCVD, high-risk indicators for ASCVD on metformin, SGLT2i, and/or GLP1-RA (if it is affordable) should be added independent of HbA1c (9, 10, 17, 21, 22, 27).

Recommendation 17: For people with HF on metformin, SGLT2i with proven HF benefit should be considered independent of HbA1c (9, 17, 21, 22, 27).

Recommendation 18: In people with CKD on metformin (eGFR ≥30 ml/min/1.73 m^2), SGLT2i should be considered independent of HbA1c level. If SGLT2i is not tolerated or contraindicated, GLP1-RA with proven CVD benefit is recommended (9, 11, 17, 21, 22, 25, 26, 27).

Recommendation 19: If combination therapy is indicated and cost of treatment is an issue, metformin in combination with pioglitazone, dipeptidyl peptidase-4 inhibitor (DPP4i), or second-generation sulfonylurea (SU) might be considered (9, 11, 17, 21, 22, 25, 27).

Recommendation 20: For all patients at risk of hypoglycemia, treatment should be individualized to prevent hypoglycemia. Metformin, in combination with other OADs, including SGLT2i, DPP4i, GLP1-RA, or pioglitazone, is preferred (4, 9-11, 17, 21, 22, 25, 26, 27).

Recommendation 21: If combination therapy is indicated and metformin is not tolerated or contraindicated, two drugs with different complementary mechanisms of action should be considered (17, 21, 22, 25, 27).

Recommendation 22: For people on two OADs, triple therapy should be considered if the glycemic target is not achieved. FDC therapy is preferred (3, 9, 17, 21, 22, 25, 27).

Recommendation 23: Quadruple therapy might be considered in people on triple therapy and with HbA1c ≤1% above the target (9).

Question 6: What are the factors affecting the choices of combination therapy?

Recommendation 24: For people with low ASCVD risk, metformin combined with one OAD from all available medication classes (DPP-4i, SGLT2i, GLP1-RA, SU, or thiazolidinedione (TZD)) is recommended (12).

Recommendation 25: For people with established ASCVD or with indicators of high ASCVD risk on either SGLT2i or GLP1-RA and with HbA1c above the target, a combination of SGLT2i and GLP1-RA should be considered (12).

Recommendation 26: For people with HF or CKD, combinations of SGLT2i and GLP1-RA with proven efficacy

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are recommended independent of glycemic control (4, 9, 17, 21, 22, 25, 27).

Figure 1 illustrates the treatment algorithm in T2DM.

Injectable therapy

Question 7: When injectable therapy is indicated?

Recommendation 27: In people who do not reach HbA1c target with a combination of OADs and with HbA1c <10%, GLP1-RA should be considered if it is affordable (3, 9, 27).

Recommendation 28: DPP4i should be discontinued if GLP1-RA is added (3, 9, 27).

Recommendation 29: In people on a combination of OADs with severe hyperglycemia and or signs and symptoms of a catabolic state, insulin therapy should be considered as the first option (3, 9, 27).

Recommendation 30: Injectable therapy in combination with OADs should be considered in people on the triple combination of OADs and with HbA1c 1% above the target (3, 9, 27).

Recommendation 31: GLP1-RA may also be considered in the context of overweight/obesity (3, 9).

Recommendation 32: If injectable therapy is indicated and GLP1-RA is not affordable, basal insulin is the most convenient initial insulin regimen and can be added to metformin or other combinations of OADs (3, 9, 27).

Recommendation 33: If a patient with T2DM is on a basal insulin regimen, add-on therapy with GLP1-RA should be considered when basal insulin need is greater than 0.5 U/kg/day. An alternative is a fixed-ratio combination of basal insulin and GLP1-RA. If GLP1-RA is not affordable, adding prandial insulin prior to the main meal or before the meal with greater glucose excursion (based on self-monitoring of blood glucose (SMBG) is indicated (3, 9, 27).

Recommendation 34: In patients who have not reached HbA1c target on basal insulin and with a premeal prandial injection, stepwise addition of further prandial insulin or switching to twice daily premixed/co-formulation insulin is recommended (3, 9, 27).

Recommendation 35: In people who need renal replacement therapy, insulin is the preferred treatment option (3, 9, 27).

Question 8: Which treatment options should be considered when hypoglycemia is a major concern?

Recommendation 36: In patients at risk of hypoglycemia or with a documented history of hypoglycemia, oral or injectable therapy with minimal or no hypoglycemic risk, namely SGLT2i, DPP4i, GLP1-RA, or TZDs, should be considered (9, 27).

Recommendation 37: If SU is indicated, new generation SU with minimal or no hypoglycemic risk is preferred (3, 9, 27).

Recommendation 38: Patient empowerment programs should be implemented to recognize, prevent, and treat hypoglycemia if SU/insulin is a treatment option. SMBG is an important tool to document hypoglycemia (3, 9, 27).

Recommendation 39: For insulin initiation, insulin analogs are preferred, considering a lower risk of hypoglycemia (3, 4, 9, 27).

Recommendation 40: Consider insulin analogs to control blood glucose levels in people with frequent and/or severe

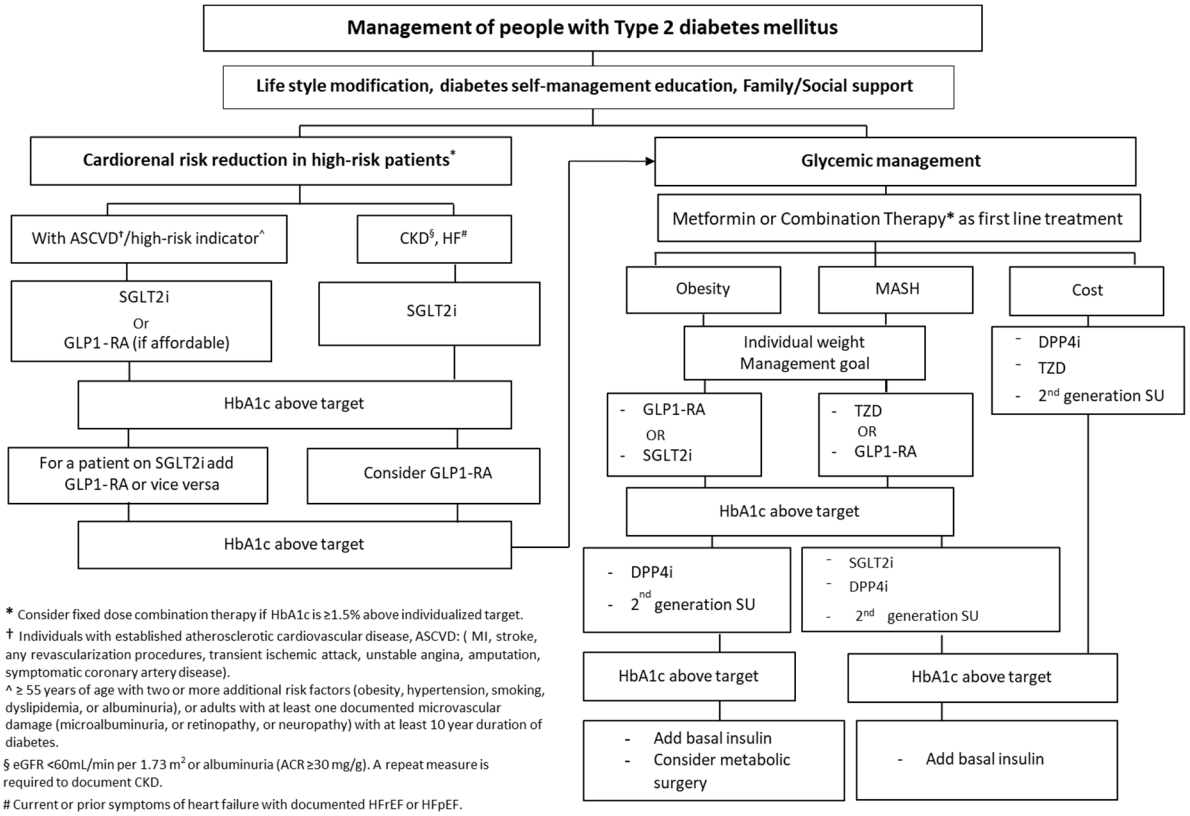

Figure 1. Treatment algorithm in people with T2DM

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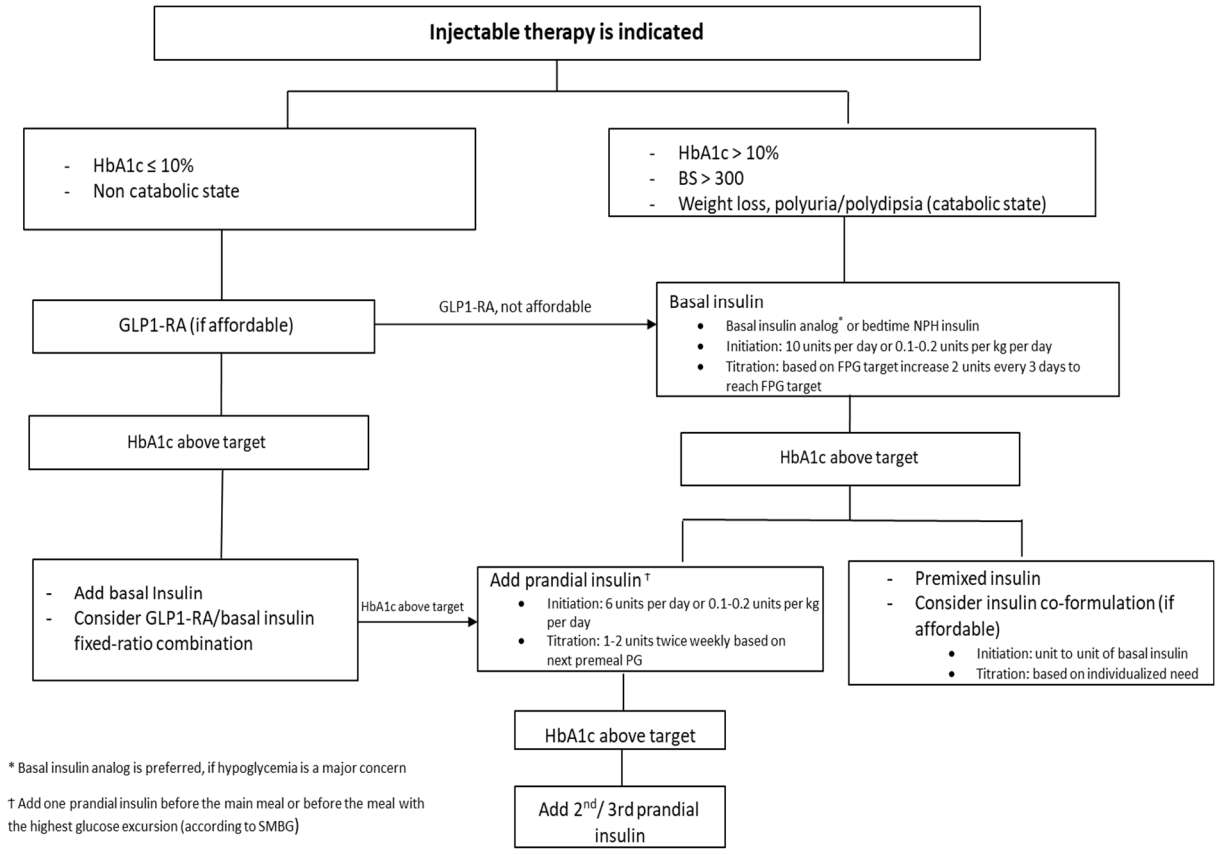

Figure 2. Flowchart of injectable therapy

hypoglycemia on human insulin therapy (9, 27).

Figure 2 illustrates the flow chart of injectable therapy.

Metabolic Dysfunction-Associated Steatosis Liver Disease in People with T2DM

Question 9: What is the appropriate strategy for MASLD screening in people with T2DM?

Recommendation 41: Fibrosis index based on four factors (FIB4) score assessment should be used as a screening tool and repeated annually in all people with T2DM, specifically those with (28, 29):

- Non-optimal metabolic control
- General obesity/abdominal obesity
- Hypertriglyceridemia
- High ALT level
- Ultrasound evidence of fatty liver disease

Question 10: What are the best treatment options for people with T2DM and MASLD?

Recommendation 42: In people with a low risk of fatty liver disease, lifestyle interventions targeting a 7-10% reduction in body weight, as well as treatment intensification of cardiovascular risk factors, are recommended (28, 29).

Recommendation 43: People with a high risk of fatty liver disease should be referred to specialized centers. To manage hyperglycemia and address fatty liver disease, in addition to lifestyle interventions, pioglitazone is recommended as the first-line treatment. GLP1-RA and SGLT2i can be considered as alternative options (28, 29).

Risk stratification based on FIB4 score cut-off values and management algorithm in people with T2DM and MASLD is demonstrated in Figure 3.

Conclusion

This consensus provides Iranian healthcare professionals with the latest evidence in the management of people with T2DM. It emphasizes on the importance of a comprehensive management approach that includes lifestyle as well as pharmacological interventions, considering cardiorenal risk reduction. The consensus also addresses the optimal management of metabolic dysfunction-associated steatosis liver disease (MASLD) in people with T2DM. In addition, it explores the significance of timely initiation of a combination of OADs treatment from the start as well as appropriate injectable therapy when indicated. The consensus also provides healthcare professionals with practical recommendations to achieve optimal glycemic control and to improve healthcare outcomes.

Authors' Contributions

Conceptualization: AE, MM, FHG, FH and MEK. Data curation: AE, MM, FHG, FH, MAA, HRAM, MHD, FG, SAJ, SK, MM, ZM, MN, HR, MS, AZ and MEK. Methodology/formal analysis/validation: AE, MM, FHG, FH, MAA, HRAM, MHD, FG, SAJ, SK, MM, ZM, MN, HR,

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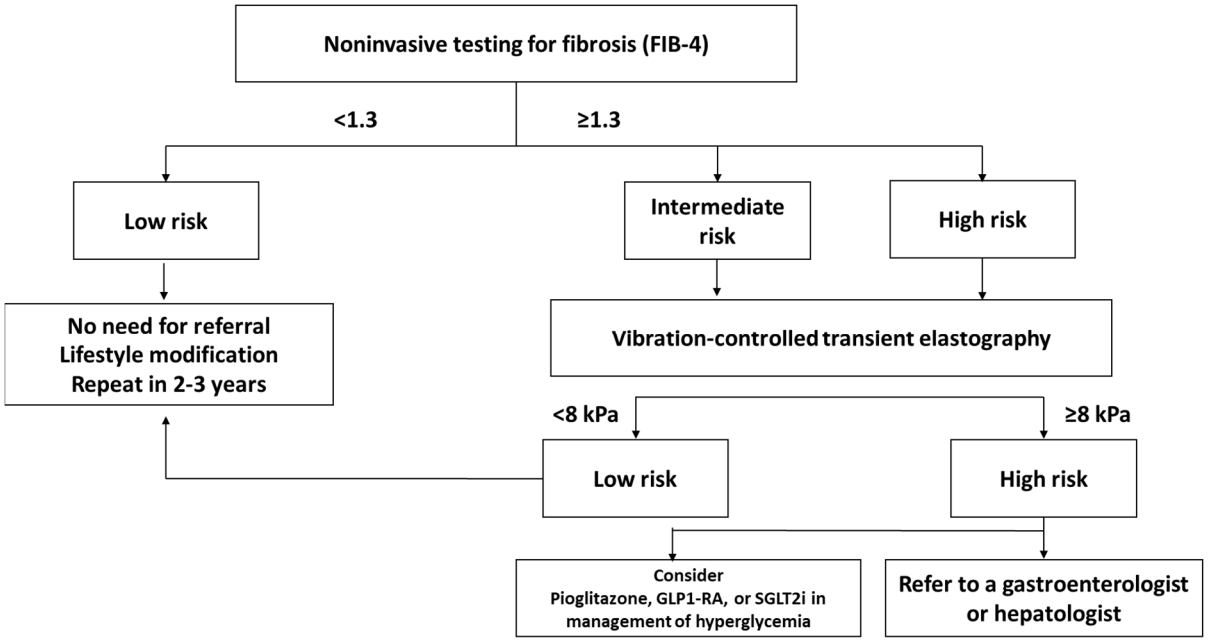

Figure 3. Flowchart of risk stratification based on FIB4 score cut-off values and management algorithm in people with T2DM and MASLD

MS, AZ and MEK. Writing the original draft: AE, MM, FHG, FH, MAA, HRAM, MHD, FG, SAJ, SK, MM, ZM, MN, HR, MS, AZ and MEK. Writing, reviewing & editing: AE, MM and MEK.

Ethical Considerations

Not applicable.

Acknowledgment

Not applicable.

Conflict of Interests

Abidi Pharmaceuticals sponsored group meetings and logistic arrangements. However, the company did not have any role in scientific discussions and development of the consensus recommendations.

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