Taste Issues with Metformin Hydrochloride Formulations and Patient Compliance by Elderly Users

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Diabetes mellitus is a chronic illness requiring long-term administration of medication. Although fixed-dose antihyperglycemic medications offer less flexibility in terms of adjustment of the dosing of the individual components, the benefits that may be achieved, such as increased acceptability, make these medications worth trying [1].

Acceptability is the overall ability of the patient and caregiver (commonly defined as “user”) to use a medicinal product as intended. The acceptability of a medicinal product has a significant impact on the patient's adherence and, consequently, on the safety and efficacy of the product [2]. It is generally driven by characteristics of the user (age, ability, disease type, and physiologic conditions) and by the characteristics of a medicinal product, such as palatability, swallowability, the required dose and frequency, the selected administration device, and the actual mode of administration [2]. Notably, non-compliance is a major health care problem in all therapeutics areas, with estimates of nonadherence rates ranging from 30 to 60%, with higher rates in symptom-free patients [1].

There is no doubt that the oral route is the most preferred route in the administration of medicinal products and drug therapy. However, oral administration requires a satisfactory palatability and a functioning swallowing process. Palatability could be defined as the overall appreciation of an (often oral) medicine by organoleptic properties such as smell, taste, aftertaste and texture (mouthfeel), and possibly also vision and sound. It is determined by the characteristics of the components, the active pharmaceutical ingredient (API) and used excipients, and the way the API is formulated. Not only should a medicinal product not taste and smell unpleasant, it should have acceptable mouthfeel (viscosity, grittiness) and appearance (visual aspect, size and shape) to have a positive influence on patient compliance [2].

Physiological properties such as temperature and texture affect the perception of taste. Moreover, human taste appears to change with age. Likewise, psychological factors can influence taste perception: a childhood memory of badly formulated cough medicine can significantly modify taste perception of a modern formulation. Such factors highlight the role of the taste in manufacturing a product that should improve patient compliance [3]. Besides, the bitterness of human pharmaceutical medicines plays a critical role in patient compliance as the oral administration of bitter drugs is often hampered by their unpleasant taste. This leads to noncompliance and thus decreases therapeutic efficacy, especially in case of children and elderlies [4,5].

Metformin HCl is the focus of several works related to its unpleasant and bitter taste [6-10]. Additionally, side effects and the need for two to three times a day administration can reduce patient compliance and hinder a more successful therapy [11]. Gastrointestinal side-effects, such as bloating, flatus and diarrhea, occur in about 30% of patients and therefore metformin HCl is recommended to be taken with meals to minimize these gastrointestinal side effects [12].

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Swallowing issues and the development of clinically significant dysphagia show increased prevalence with increasing age [13]. The individual swallowing capacity might differ significantly in older adults, while the overall swallowing capability is declining with increasing age [14]. A study performed by Nilsson, et al. [15] showed that the mean oral-pharyngeal transit time in healthy adults is around 0.58 seconds. In contrast, this situation is drastically changed in the elderly population leading to an increase in swallowing time to around 1.23 seconds. Swallowing functions underlie a normal aging process and can be seriously impacted by diseases and disease progression as well as by drug substances. These age-related changes in swallowing functions are attributed to physiological, anatomical, motoric and sensory alterations. Furthermore, swallowing might also be impacted by a decline in saliva production or xerostomia, which affects bolus formation and smooth deglutination [13].

Under those circumstances, the oral administration of metformin HCl tablets becomes a challenge since the usual doses of oral treatment with metformin HCl (500 to 1000 mg) generates tablets with relatively large dimensions. In the German market, for instance, the absence of alternative dosage forms, or age-adapted dosage forms, shows a lack of consideration to this special population: all 26 available products containing metformin HCl are film coated tablets with doses between 500 and 1000 mg [16].

Recently, aiming to improve patient compliance regarding the administration of metformin HCl, oral solid dosage forms presenting taste-masked properties and focusing on an easy administration were developed and showed the increasing concern with the difficulties presented by diabetic patients with administration of metformin HCl [7,10,17-20].

However, more effort is still required to improve patient compliance regarding the administration of antidiabetic APIs, such as metformin HCl, focusing on the patient relationship with the dosage form and its administration. This situation is even more prominent highlighted in geriatric patients and should also be considered in further studies.

Bibliography

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