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The pivotal role of basal insulin replacement in the treatment of diabetes mellitus

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Over the last few years, two new long-acting insulin analogues have been introduced to the market, namely insulin degludec (IDegl) and insulin glargine-U300 (Gla-300). These innovations follow by few years the availability of the first soluble long-acting insulins (glargine and detemir, in year 2000 and 2004, respectively). Thus, in the last 15 years, there have been several innovations about basal insulins, in contrast to the long "medioeval" time of immobilism of the NPH era from year 1946 to 2000, where for more than fifty years no alternative to NPH was available. The "renaissance" of basal insulin initiated with the introduction of soluble preparations which have the advantage of lower variability vs NPH since they do not need re-suspension prior to injection. Glargine U100 and detemir are both better than NPH also because of lower peak and therefore reduce the risk of hypoglycaemia especially at night. Any time a new basal insulin is compared with the standard insulin in phase III studies, the glucose lowering efficacy is always non-inferior (this was the case with glargine U100 and detemir vs NPH, and it is nowdays with IDegl or Gla-300 vs glargine U100). However, the advantage of glargine and detemir vs NPH has been reduction of nocturnal hypoglycaemia. Interestingly, both IDegl and Gla-300 reduce the nocturnal and 24-h hypoglycaemia risk vs glargine. The risk reduction of hypoglycaemia vs glargine has been demonstrated in phase III studies for IDegl (BEGIN studies) and for Gla-300 (EDITION studies). Overall with both IDegl and Gla-300, the risk reduction of nocturnal hypoglycaemia in T2DM is 30% and that of 24-h hypoglycaemia 15%. Both IDegl and Gla-300 reduce also the risk of hypoglycaemia in T1DM. Since IDegl and Gla-300 have been studied both vs glargine, but not directly vs each other, the relative differences between IDegl and Gla-300 are not known. However, initial head-to-head PK/PD studies are being published, and clinical studies in T1DM and T2DM are in progress. This will make it possible to better understand similarities and differences between IDegl and Gla-300 and to identify characteristics of patients who will best benefit from one vs the other basal insulin.