Case study*

Diagnosing type 2 diabetes in a primary care practice

Overview Click any of the options below to go to that section:

***Fictitious case, created for illustrative purposes only by a healthcare professional**

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Prescribing information and adverse event reporting information can be found at the end of this case study.
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Presentation details

- BW* is a 64-year-old woman
- Presented to the nurse practitioner (NP) with a history of thrush
  - Had self-treated the condition, was concerned at its recurrence
  - Overweight (BMI 30 kg/m^2), but considered herself reasonably active through dog walking
  - Non-smoker and drank alcohol in moderation

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Go to **Initial assessment**

Initial assessment

- The NP considered type 2 diabetes (T2D) as a likely cause of BW's recurrent infections
  - Blood tests for HbA_{1c}, lipids and renal function were arranged
  - BP was also measured: 135/89 mmHg
- Basic lifestyle advice was discussed and a follow-up review arranged

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Go to **Review after 1 week with test results**

Review after 1 week with test results

- BW returned to discuss the results with the NP
- Blood test results:
  - HbA_{1c}: 64 mmol/mol (8.0%)
  - Total cholesterol: 4.8 mmol/L
  - Estimated glomerular filtration rate (eGFR): >60 mL/min/1.73m^2

- Cardiovascular risk assessment:
  - T2D is frequently accompanied by other features of the metabolic syndrome (hypertension, obesity and dyslipidaemia), increasing the risk of cardiovascular disease (CVD)[1]
  - NICE recommends using the QRISK2 tool to assess the 10 year risk of developing CVD[2]
  - BW's QRISK2 score was 11%

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Go to **Considerations for management**

Considerations for management (i)

- As BW was currently asymptomatic, a repeat HbA_{1c} test was arranged to confirm the diagnosis of type 2 diabetes (T2D)[3]
- Implications of T2D were discussed with BW:
  - This warrants sensitive handling as a diagnosis of T2D in itself can have an adverse effect on the individual's quality of life[4]
  - The important role of lifestyle changes in improving her future health was reinforced
  - She was referred to the practice dietician, the local structured education programme, and provided with Diabetes UK literature
  - Department of Health recommendations for physical activity per week: ≥150 minutes (2.5 hours) of moderate intensity activity in bouts of 10 minutes or more[5]
  - The importance of early, effective glycaemic control in T2D was demonstrated by the 'legacy' effect of the United Kingdom Prospective Diabetes Study (UKPDS)[6]; BP and lipids management are also key priorities in T2D clinical care[7]
  - Even modest weight loss (5–10% of body weight) benefits glycaemic control, BP and lipid levels[8]

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Go to **Considerations for management (ii)**

Considerations for management (ii)

- Together with the NP, BW opted to try to improve her results through lifestyle changes
  - BW decided to follow a 5:2 diet plan during the next 3 months (reducing her calorie intake for 2 days per week, eating normally on the other days)
  - Based on BW's QRISK2 score and her intention to make lifestyle changes, no medication was prescribed for primary prevention of CVD at this time[2]
  - A review (including a new HbA_{1c} and lipid blood test) was arranged for 3 months' time

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Go to **Follow-up**

Follow-up

- After 3 months:
  - BW was delighted to have lost 3 kg
  - HbA_{1c} was 59 mmol/mol (7.6%)
  - Total cholesterol was 4.3 mmol/L
  - BP average was 130/80 mmHg

- For people with type 2 diabetes (T2D) who are on lifestyle interventions alone, NICE recommends a target HbA_{1c} of 48 mmol/mol (6.5%) and to consider medication above this level[9]
  - Clinical inertia has been responsible for delays in initiating or escalating therapy in T2D, which adversely affects outcomes[10]
  - If the agreed HbA_{1c} target is not achieved after 3 months, escalation of glucose-lowering therapy is advocated[7]

- BW agreed to start metformin at a low dose
  - The NP explained potential gastro-intestinal side effects and gradual dose titration
- A review (including HbA_{1c} and lipid tests) was arranged for 3 months' time to assess the need for further medication and reinforcement of lifestyle advice
- BW was planning to attend her structured education course ahead of her next review

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Go to **Clinical implications**

Clinical implications

1. Recurrent infections are a common symptom in type 2 diabetes, so healthcare professionals should investigate if a person has not previously been diagnosed as diabetic
2. Early, effective control of BP, lipids and blood glucose in people with type 2 diabetes leads to better outcomes in later life
3. Patient participation is paramount
4. A diagnosis of diabetes has a profound effect on the individual
5. Regular follow-up and action prevents clinical inertia

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References

1. Alberti KG, Zimmet P, Shaw J (2006) *Diabet Med* **23**: 469–80
2. NICE (2014) *Cardiovascular disease: risk assessment and reduction, including lipid modification (CG181)*. Available at: http://bit.ly/29vrw1I (accessed 06.06.2018)
3. NICE (2016) *Clinical Knowledge Summaries. Diabetes – type 2. Diagnosis – Adults.* Available at: http://bit.ly/2ksp8Pj (accessed 06.06.2018)
4. Nash J (2014) *Journal of Diabetes Nursing* **18**: 137–41
5. Department of Health (2011) *Physical Activity Guidelines for Adults. Factsheet 4*. Available at: http://bit.ly/1hfgFq2 (accessed 06.06.2018)
6. Holman RR et al (2008) *N Engl J Med* **359**:1577–89
7. Inzucchi SE (2015) *Diabetes Care* **38**: 140–9
8. Wing RR et al (2011) *Diabetes Care* **34**: 1481–6
9. NICE (2015) *Type 2 diabetes in adults: management (NG28).* Available at: http://bit.ly/1PDex0p (accessed 06.06.2018)
10. Paul SK (2015) *Cardiovasc Diabetol* **14**: 100

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Prescribing information PI

Prescribing information

TRAJENTA® (linagliptin) 5 mg film-coated tablets

Film-coated tablets containing 5 mg linagliptin. **Indication:** Trajenta is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control as: monotherapy when metformin is inappropriate due to intolerance, or contraindicated due to renal impairment; combination therapy in combination with other medicinal products for the treatment of diabetes, including insulin, when these do not provide adequate glycaemic control. **Dose and Administration:** 5 mg once daily. If added to metformin, the dose of metformin should be maintained and linagliptin administered concomitantly. When used in combination with a sulphonylurea or with insulin, a lower dose of the sulphonylurea or insulin, may be considered to reduce the risk of hypoglycaemia. Renal impairment: no dose adjustment required. Hepatic impairment: pharmacokinetic studies suggest that no dose adjustment is required for patients with hepatic impairment but clinical experience in such patients is lacking. Elderly: no dose adjustment is necessary based on age however, clinical experience in patients > 80 years of age is limited and caution should be exercised when treating this population. Paediatric population: the safety and efficacy of linagliptin in children and adolescents has not yet been established. No data are available. Take the tablets with or without a meal at any time of the day. If a dose is missed, it should be taken as soon as possible but a double dose should not be taken on the same day. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and Precautions:** Linagliptin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Caution is advised when linagliptin is used in combination with a sulphonylurea and/or insulin; a dose reduction of the sulphonylurea or insulin may be considered. Acute pancreatitis: In post-marketing experience of linagliptin there have been spontaneously reported adverse reactions of acute pancreatitis. Patients should be informed of the characteristic symptoms of acute pancreatitis. If pancreatitis is suspected, Trajenta should be discontinued; if acute pancreatitis is confirmed, Trajenta should not be restarted. Caution should be exercised in patients with a history of pancreatitis. Bullous pemphigoid: If bullous pemphigoid is suspected, Trajenta should be discontinued. **Interactions:** Linagliptin is a weak competitive and a weak to moderate mechanism-based inhibitor of CYP isozyme CYP3A4, but does not inhibit other CYP isozymes. It is not an inducer of CYP isozymes. Linagliptin is a P-glycoprotein substrate and inhibits P-glycoprotein mediated transport of digoxin with low potency. Based on these results and *in vivo* interaction studies, linagliptin is considered unlikely to cause interactions with other P-gp substrates. The risk for clinically meaningful interactions by other medicinal products on linagliptin is low and in clinical studies linagliptin had no clinically relevant effect on the pharmacokinetics of metformin, glibenclamide, simvastatin, warfarin, digoxin or oral contraceptives (please refer to Summary of Product Characteristics for information on clinical data). **Fertility, pregnancy and lactation:** Avoid use during pregnancy. A risk to the breast-fed child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from linagliptin therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. No studies on the effect on human fertility have been conducted for linagliptin. **Undesirable effects:** Adverse reactions reported in patients who received linagliptin 5 mg daily as monotherapy or as add-on therapies (frequencies identified from pooled analysis of placebo-controlled studies) in clinical trial and from post-marketing experience. The adverse reactions are listed by absolute frequency. Frequencies are defined as very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (<1/10,000) or not known (cannot be estimated from the available data). Very common: hypoglycaemia (combination with/add-on to metformin and sulphonylurea). Common: lipase increased (monotherapy; combination with/add-on to metformin; combination with/add-on to metformin and sulphonylurea; combination with/add-on to insulin; combination with/add-on to metformin and empagliflozin). Uncommon: nasopharyngitis (monotherapy; combination with/add-on to metformin; combination with/add-on to insulin); hypersensitivity e.g. bronchial hyperreactivity (monotherapy; combination with/add-on to metformin; combination with/add-on to metformin and sulphonylurea; combination with/add-on to insulin); cough (monotherapy; combination with/add-on to metformin; combination with/add-on to insulin); pancreatitis (combination with/add-on to insulin); constipation (combination with/add-on to insulin); rash (monotherapy; combination with/add-on to metformin; combination with/add-on to metformin and sulphonylurea; combination with/add-on to insulin); amylase increased (combination with/add-on to metformin; combination with/add-on to metformin and sulphonylurea; combination with/add-on to metformin and empagliflozin). Rare: angioedema (monotherapy; combination with/add-on to metformin; combination with/add-on to metformin and sulphonylurea; combination with/add-on to insulin); urticaria (monotherapy; combination with/add-on to metformin; combination with/add-on to metformin and sulphonylurea; combination with/add-on to insulin); amylase increased (monotherapy). Not known: nasopharyngitis (combination with/add-on to metformin and sulphonylurea; combination with/add-on to metformin and empagliflozin); hypersensitivity e.g. bronchial hyperreactivity (combination with/add-on to metformin and empagliflozin); cough (combination with/add-on to metformin and sulphonylurea; combination with/add-on to metformin and empagliflozin); pancreatitis (monotherapy; combination with/add-on to metformin; combination with/add-on to metformin and sulphonylurea; combination with/add-on to metformin and empagliflozin); bullous pemphigoid (monotherapy; combination with/add-on to metformin; combination with/add-on to metformin and sulphonylurea; combination with/add-on to insulin); amylase increased (combination with/add-on to insulin). Prescribers should consult the Summary of Product Characteristics for further information on side effects. **Pack sizes and NHS price:** 28 tablets £33.26. **Legal category:** POM. **MA number:** EU/1/11/707/003. **Marketing Authorisation Holder:** Boehringer Ingelheim International GmbH, D-55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. **Prepared in** April 2017.

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Adverse events should also be reported to Boehringer Ingelheim Drug Safety on 0800 328 1627 (freephone).

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