Patient case study

Sialanar®

400mcg/ml glycopyrronium bromide equivalent to 320mcg/ml glycopyrronium

Meet Tim...

A positive response to Sialanar® in the treatment of anterior and posterior sialorrhoea

Reported by
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Patient profile

The patient (Tim) is a 16 year old male who has a Neurodevelopmental Disorder with Hypotonia, Seizures and Absent Language (NDHSAL), due to a heterozygous mutation in the HECW2 gene.

He is GMFCS level 5 equivalent, wheelchair bound and has been diagnosed with the following:

- Severe learning disability
- Secondary intractable epilepsy
- Microcephaly and optic atrophy
- Central hypotonia with increased peripheral spasticity
- Significant scoliosis
- Bilaterally dislocated hips
- Unsafe swallow so NBM
- Feeding issues, managed via a gastronomy tube

Tim has been prescribed the following medication:

- Baclofen 10mg four times a day
- Sodium valproate 200mg twice daily
- Topiramate 75mg twice daily
- Lansoprazole 15mg once daily
- Emergency medication Buccolam (Buccal Midazolam) 7.5mg as needed for prolonged seizure lasting beyond five minutes

Case history

Due to excessive drooling (both anterior and posterior), Tim was referred for respiratory physiotherapy assessment and to assess whether suction was required. His parents main concerns were that Tim was producing more secretions, particularly during the night and his ability to clear the secretions was reduced. This contributed to a number of significant physical and social issues impacting quality of life for Tim and the family:

- High burden of care, requiring 1:1, 24 hours a day care
- Frequent changes in position over 24 hours, resulting in lack of sleep for Tim and his family
- Frequent change of clothes, bed sheets and towel (change towel approx. 6x daily), resulting in an increased burden on Tim's mother
- Varying degrees of anterior and posterior drooling, dependent on position
- Episodes of choking / coughing on oral secretions which Tim was not always able to clear independently, resulting in signs of respiratory distress, such as increased work of breathing, causing anxiety and concern for family who are unable to clear Tim's secretions
- Vomiting possibly due to coughing, issues with feed or reflux, resulting in significant loss of weight

Prescribing information can be found at the end of this document

Assessment and examination

Tim was at risk of chest infections due to his limited mobility and inability to reposition independently. He was also at risk of aspirating his oral secretions, due to his unsafe swallow. He has a reduced lung and chest capacity due to severe scoliosis and a rib cage deformity.

A patient assessment was carried out and determined that:

- There were no signs of respiratory distress, on auscultation clear breath sounds throughout and no visible oral secretions
- He had not experienced any recent chest infections or been prescribed antibiotics for a chest infection
- Tim's last chest x-ray showed no focal collapse or consolidation
- Secretions reported were loose and clear but could sometimes be thick

Excessive drooling may require treatment with an anticholinergic when:

- Facial skin irritation
- Chest infections
- Worsening cough due to secretions
- Breathing issues
- Distressed patient and family

Management and treatment

To help Tim clear secretions independently, positioning advice was reiterated to the family. However, due to the large volume of oral secretions and vomiting, the use of an anticholinergic medication was also recommended after discussions with a consultant paediatrician.

Tim was initially prescribed ½ hyoscine patch for the first week, which was increased to one patch thereafter.

Although vomiting reduced, no decrease in excessive secretions was reported and multiple towel changes were still required, particularly overnight.

Treatment review: the use of Sialanar®

A treatment review was undertaken, during which the hyoscine patch was discontinued. After 24 hours, Sialanar® was prescribed and administered.

Sialanar® was started at 1.2ml per dose for the first week, before titrating up to the appropriate dose for Tim (2.4ml TDS).

Treatment results with Sialanar®

Tim experienced improved quality of life outcomes, including:

Improvements in symptoms:

- Less vomiting, choking and coughing
- No suction required
- Reduced risk of aspiration and chest infections

Improved quality of life:

- Fewer interventions required by school nurses
- Improved sleep for both patient and family due to fewer changes overnight
- Patient feeling more settled
- Less anxiety and concerns for family

Summary

The excessive drooling which caused physical and psychological issues to both patient and family was managed effectively due to a switch to Sialanar® (licensed for the symptomatic treatment of severe sialorrhoea in children and adolescents aged three years and older, with chronic neurological disorders).

Changing treatment significantly improved Tim and his family's quality of life. With an improvement in his coughing and vomiting episodes, he has also manged to increase his weight through dietitian assistance. Child and family are now happy that his drooling is under control.

Prescribing Information (UK and Republic of Ireland)

Sialanar (400 mcg/ml glycopyrronium bromide, equivalent to 320 mcg/ml glycopyrronium) oral solution. Please refer to the full Summary of Product Characteristics (SmPC) before prescribing.

Active ingredient: 1ml contains 400mcg glycopyrronium bromide (equivalent to 320 micrograms glycopyrronium). **Indication:** Symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders. **Dosage:** Start with approximately 12.8 micrograms/kg body weight of glycopyrronium per dose, three times per day. Increase dose weekly until efficacy is balanced with side effects. Titrate to maximum individual dose of 64 mcg/kg body weight glycopyrronium or 6 ml three times a day, whichever is less. Monitor at least 3 monthly for changes in efficacy and/or tolerability and adjust dose if needed. Not for patients less than 3 or over 17 years old as Sialanar is indicated for the paediatric population only. ***Renal impairment:*** Reduce dose by 30%, in mild/moderate renal failure. **Method of Administration:** Oral use only. Dose at least one hour before or two hours after meals or at consistent times with respect to food intake. Avoid high fat food. Flush nasogastric tubes with 10 ml water. **Contraindications:** Hypersensitivity to active substance or excipients; pregnancy and breast-feeding; glaucoma; urinary retention; severe renal impairment/dialysis; history of intestinal obstruction, ulcerative colitis, paralytic ileus, pyloric stenosis; myasthenia gravis; concomitant treatment with potassium chloride solid oral dose or anticholinergic drugs. **Undesirable effects:** Adverse reactions more common with higher doses and prolonged use. In placebo-controlled studies (≥15%) dry mouth, constipation, diarrhoea and vomiting, urinary retention, flushing and nasal congestion. In paediatric literature; *very common:* irritability, reduced bronchial secretions; *common:* upper respiratory tract infection, pneumonia, urinary tract infection, agitation, drowsiness, epistaxis, rash, pyrexia. The Summary of Product Characteristics should be consulted for a full list of side effects. **Special warnings and precautions:** Monitor anticholinergic effects. Carer should stop treatment and seek advice in the event of constipation, urinary retention, pneumonia, allergic reaction, pyrexia, very hot weather or changes in behaviour. For continuous or repeated intermittent treatment, consider benefits and risks on case-by-case basis. Not for mild to moderate sialorrhoea. Use with caution in cardiac disorders; gastro-oesophageal reflux disease; pre-existing constipation or diarrhoea; compromised blood brain barrier; in combination with: antispasmodics, topiramate, sedating antihistamines, neuroleptics/antipsychotics, skeletal muscle relaxants, tricyclic antidepressants and MAOIs, opioids or corticosteroids. Sialanar contains 2.3 mg sodium benzoate (E211) in each ml. Patients require daily dental hygiene and regular dental checks. Thicker secretions may increase risk of respiratory infection and pneumonia. Moderate influence on ability to drive/use machines. **Fertility, pregnancy, and lactation:** Use effective contraception. Contraindicated in pregnancy and breast feeding. **Legal classification:** POM. **Further information available on request from the Marketing Authorisation Holder. Date of last revision of prescribing information:** May 2023.

For the United Kingdom

Marketing Authorisation Holder: Proveca Pharma Ltd. 2 Dublin Landings, North Wall Quay, Dublin 1, Ireland. **Pack Sizes & NHS price**: Sialanar 250 ml bottle £320. Sialanar 60ml Bottle £76.80. **Marketing Authorisation Numbers:** ***Great Britain:*** PLGB 42588/0003. ***Northern Ireland:*** Sialanar 250 ml bottle - EU/1/16/1135/001; Sialanar 60ml Bottle - EU/1/16/1135/002

Adverse events should be reported.
Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Proveca Limited.
Phone: +44 333 200 1866
E-mail: medinfo@proveca.com

For the Republic of Ireland

Marketing Authorisation Holder: Proveca Pharma Ltd. 2 Dublin Landings, North Wall Quay, Dublin 1, Ireland. **Pack Sizes:** Sialanar 250 ml Bottle. Sialanar 60ml Bottle (hospital use only). **Marketing Authorisation Numbers:** Sialanar 250 ml bottle - EU/1/16/1135/001; Sialanar 60 ml Bottle - EU/1/16/1135/002

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UK-SIA-23-0082 July 2023