Control of drooling using transdermal scopolamine skin patches. A case report

Abigail Mato Montero [1], Jacobo Limeres Posse [2], Inmaculada Tomás Carmona [3], Javier Fernández Feijoo [4], Pedro Diz Dios [5]

(1) Tutora clínica
(2) Profesor ayudante
(3) Profesora interina
(4) Profesor asociado
(5) Profesor titular
Departamento de Estomatología. Unidad de Pacientes Especiales. Facultad de Medicina y Odontología. Universidad de Santiago de Compostela

Correspondence:
Dr. Pedro Diz Dios
Unidad de Pacientes Especiales
Facultad de Medicina y Odontología.
Universidad de Santiago de Compostela
C/ Entrerríos sn
15782 Santiago de Compostela. Spain
E-mail. pdiz@usc.es

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Abstract
Transdermal scopolamine has been shown to be very useful in the management of drooling, particularly in patients with neurological or neuropsychiatric disturbances or severe developmental disorders. In this paper, we present the case of a 24-year-old patient with a diagnosis of cerebral palsy and a severe problem of drooling, exacerbated by marked mandibular prognathism. After exclusion of other therapeutic alternatives, it was decided to use sustained-release transdermal scopolamine patches (Scopoderm TTS). This technique consists of the application every three days of a patch with 1.5 mg of scopolamine in the area of the mastoid apophysis; the patch releases a dose of 0.5 mg of the active substance over each 24 hour period. The patient underwent periodic clinical and laboratory follow-up over a period of three years, achieving satisfactory results with no significant undesirable effects.

Key words: *Sialorrhoea, drooling, scopolamine.*

Introduction
The terms hypersecretion, hypersalivation or ptyalism are used to describe the increase in salivary flow above normal limits (1,2). This can occur in physiological situations or in the context of a pathological process. The term sialorrhoea refers to a symptom consisting of the sensation of increased salivary flow (1,3); true sialorrhoea occurs due to an excessive stimulus of the salivary reflex whereas, in contrast, false sialorrhoea or drooling is generally due to a difficulty in swallowing the saliva, which finally escapes through the lips (3).

Drooling is usually associated with a dysfunction of oral motor activity, an insufficient swallowing capacity, a deficient oral sphincter or, less frequently, with hypersalivation (4). It is a relatively common problem in disabled individuals and has significant physical, psychosocial and aesthetic repercussions. In severe cases, it can even lead to situations of dehydration and favour the onset of infections (5). Drooling also leads to an increase in the care needs in these patients, who require their clothes and protective bibs to be changed up to 15 times a day and, on occasions, require a towel placed permanently around their neck (6).

A number of treatments has been proposed in order to palliate the problem of salivary hypersecretion and/or drooling, from techniques of motor re-education and

Table 1. Therapeutic alternatives for the control of salivary drooling.

TREATMENT	ADVANTAGES	DISADVANTAGES
Motor re-education (physiotherapy, motor stimulation, logopedia, etc)	- Non-invasive	- Requires the collaboration of the patient/tutors - Relatively unpredictable results
Pharmacological treatments (glycopyrrolate, benztropine, scopolamine, etc)	- Non-invasive - Do not require collaboration	- Adverse effects: irritability, sedation, mydriasis, urinary retention, etc.
Surgical treatments (ligation, relocation of the ducts, excision of the glands, etc)	- Do not require collaboration - High level of efficacy	- Invasive technique - Require general anaesthesia - Adverse effects: rampant caries, mucositis, etc.
Botulinum toxin	- High efficacy - Simpler and less aggressive technique than the surgical treatments	- May require general anaesthesia - Risk of muscle or nerve lesion in the adjacent regions
Radiotherapy	- Non-invasive - Does not require collaboration	- Adverse effects: osteoradionecrosis, rampant caries, mucositis, etc.
Photocoagulation of the salivary ducts	- Simpler and less aggressive technique than the surgical treatments	- Few statistical data - Adverse effects: postoperative inflammation and/or haematoma, cystic lesions, infections, etc.
Lingual acupuncture	- Simpler and less aggressive technique and the surgical treatments	- Few statistical data - Requires collaboration

physiotherapy to radical surgical procedures or radiotherapy (2,4,5) (table 1). The possible pharmacological approaches include particularly the products used in gastro-oesophageal reflux (ranitidine, cisapride, etc.) and the anticholinergic drugs (propantheline bromide, glycopyrrolate, etc), which include scopolamine.

Scopolamine basically has antiemetic and sedative-hypnotic properties. It has a duration of action of 5 to 6 hours after oral or parenteral administration, whereas its effect is maintained for 24-72 hours when it is administered in the form of transdermal patches. Its indications include the reduction of salivary secretion by blocking the parasympathetic innervation of the salivary glands (7).

The objective of this paper is to describe the treatment of drooling by the application of transdermal scopolamine skin patches in a patient with a diagnosis of cerebral palsy.

Case Report

A 24-year-old male patient with a diagnosis of cerebral palsy and psychomotor retardation. The family had requested medical consultation due to a problem of drooling that required changing the bib every hour. Physical examination of the patient confirmed the presence of drooling, exacerbated by a dolichofacial pattern characterised by significant mandibular prognathism, maxillary hypoplasia and an anterior open bite (figure 1). The lack of collaboration on the part of the patient meant that treatments requiring his active participation, such as physiotherapy or behavioural control techniques, could not be considered. Although the surgical transposition of the ducts of the submaxillary salivary glands was initially contemplated as the best therapeutic alternative, this approach was excluded after consultation with the Maxillofacial Surgery Department, due to the need to perform bimaxillary orthognathic surgery to optimise the result of the transposition. It was finally decided to use transdermal scopolamine patches (Scopoderm TTS, Novartis Consumer Health, Paris) to treat the drooling

This technique consists of the application of a skin patch behind the ear, at the level of the mastoid apophysis (figure 2). The patch releases a sustained dose of 0.5 mg of scopolamine per day and must be changed every 72 hours, alternating between the right and left sides at each change. Clinical follow-up was performed at the start of treatment and at two weeks, one month, six months and annually thereafter. Due to the limited collaboration of the patient, the clinical scale described by Thomas-Stonell and Greenburg (8) was used to quantify the drooling.

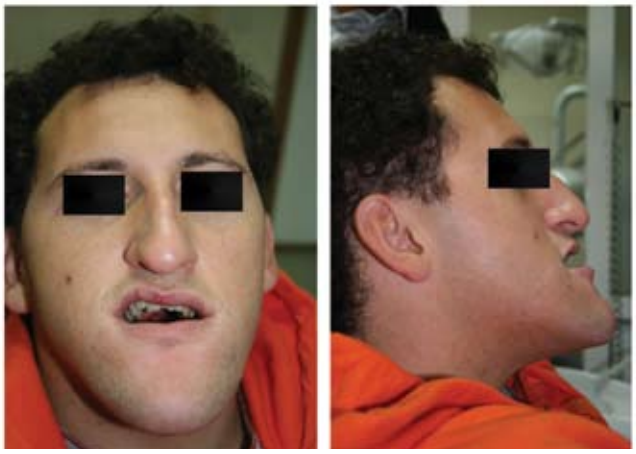

Fig. 1. Facial morphology of the patient (frontal and profile).

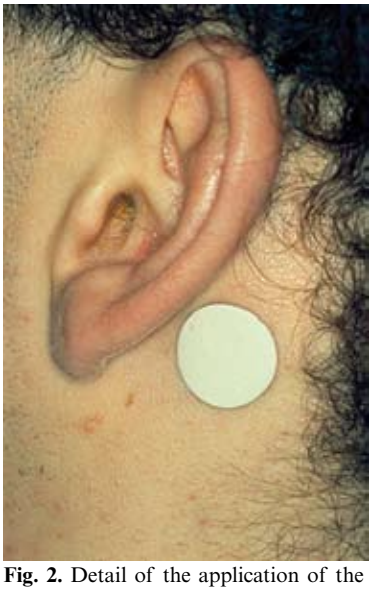

Fig. 2. Detail of the application of the scopolamine skin patch.

This scale classifies drooling into five grades: 1 = dry (no drooling); 2 = mild (humid lips); 3 = moderate (wet lips and chin); 4 = severe (clothes slightly damp); 5 = profuse (clothes, hands and objects are wet).

The clinical follow-up was completed by 6-monthly consultations with the family doctor, the neurologist and the ophthalmologist.

Blood tests (glucose, urea, creatinine, transaminases and electrolytes) were also performed to check for possible adverse effects that could initially be asymptomatic. The first blood test was performed before the first skin patch was applied, being repeated at 15 days, 3 months, 6 months and, subsequently, annually.

A significant reduction was detected in the drooling within 24 hours after the application of the first patch, and confirmed by the reduction in the number of bibs used each day (from 6/day to 1/day). After one week of treatment, the severity of the drooling fell from grade 4 to grade 2. One year after having started the treatment, the degree of drooling remained at grade 2, and the use of bibs was no longer necessary. After three years of treatment, the same therapeutic effect is maintained, with a degree of drooling of grade 1-2. Although mild oliguria has been observed, no adverse effect that requires the suspension of the treatment has been detected to date.

Discussion

A number of studies have shown a reduction in salivary secretion secondary to the administration of scopolamine (9-11). Scopolamine has therefore been used with this aim in a number of medical specialities, including Dentistry, Otorhinolaryngology and Palliative care, and in certain neurological disorders (9,10). The use of the transdermal route effectively reduces salivary secretion in approximately 67% of patients, and its effects can be observed within 15 minutes of application (4,11).

The quantification of drooling can be performed using various methods, such as the drainage or expectoration techniques or collection using a salivary ejector (12). These methods provide an objective evaluation of the quantity of saliva produced (10,11), but the limited collaboration in disabled patients requires the use of alternative methods of quantification. As in the present case, the majority of studies published use clinical scales of quantification (13,14), limiting the objectivity of the results obtained.

In this patient, the scopolamine patches were effective in reducing saliva production. Comparing scopolamine with placebo, Brodtkorb et al. (13) achieved a significant reduction in drooling at 24, 48 and 72 hours after application of the patch in 15 patients between 20 and 62 years of age with mental retardation and with problems of continual drooling (13). This result was also observed in 11 children with mental retardation with a moderate-to-severe degree of drooling (14). Dreyfuss et al. (10) reported a 30% reduction in drooling in a 40-year-old, brain-damaged patient after placement of a single scopolamine skin patch, and a 59% reduction after applying two patches simultaneously.

Pupillary dilatation and urinary retention are some of the most common undesirable effects of scopolamine patches. Lewis et al. (14) observed that 66% of patients presented pupillary dilatation and that this occurred within a few days of starting treatment. Talmi et al (11), in a study of 12 patients treated with transdermal scopolamine for short periods of time (1-6 days), reported 4 cases of blurred vision and one of urinary retention that required interruption of the treatment. The findings of these and other studies suggest that the majority of adverse effects develop within the first hours/days of treatment. In our case, the patient has presented signs of incipient urinary retention, though this has not become an adverse reaction requiring the temporary or definitive withdrawal of the treatment.

Other effects are described in the literature with lower frequencies, including tachycardia, anxiety, disorientation, hallucinations, psychosis, blurred vision and pruritus in the area of application of the patch (2,4,5).

There is no method of control of drooling that has been found to be effective in all patients. Anticholinergic drugs such as scopolamine are effective in the treatment of drooling but, according to Jongerius et al (15), it has not been established which is the most effective drug. Although it has been shown that scopolamine patches can be a useful option in the treatment of these patients, their efficacy varies between patients. We have found no prospective studies in the literature that evaluate its long-term effects; the studies of longest duration were 4-5 months (10,14). In our patient, transdermal scopolamine was an effective and safe method for reducing the drooling; however, the study population and the follow-up time will have to be increased in order to confirm its validity as a treatment for long-term use.

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