

# MP56-16 - EFFICACY AND SAFETY OF TRANSDERMAL OXYBUTYNYN VERSUS ORAL OXYBUTYNYN IN MANAGEMENT OF PEDIATRIC NEUROGENIC BLADDER

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## BACKGROUND

Neurogenic bladder is a complex condition which can have a significant impact on quality of life. Bladder dysfunction, when not managed early, can lead to renal impairment and subsequent medical complications. Children and their families also report significant social and psychological impact of poor bladder function.

Anticholinergic medications are the gold standard in pharmacotherapy for neurogenic bladder. The first line agent in Australia is oxybutynin due to cost and accessibility. Oxybutynin is available in both oral and transdermal forms. Oral oxybutynin can be associated with a significant side effect profile in some children. Additionally, compliance may be poor with oral medication due to difficulty in taking tablets in addition to inability to tolerate associated side effects. Transdermal formulations have the potential advantage of ease of use resulting in increased compliance and reduced systemic side effects. effects.

## OBJECTIVE

To compare the patient experience of transdermal versus oral oxybutynin in pediatric patients with neurogenic bladder.

## METHODS

- Retrospective study assessing patient experience of transdermal and oral oxybutynin.
- Patients with neurogenic bladder were identified via the multidisciplinary spinal rehabilitation clinic. Children under the age of 18 who had trialled transdermal and/or oral oxybutynin for greater than 6 weeks were included.
- A questionnaire and rating scale was developed to collect patient demographics and report outcomes. Efficacy, compliance and side effects were self-reported on a 5-point scale. Data was collected through phone or face-to-face interview.
- Data from patients who had trialled both oral and transdermal formulations was used to directly compare their experience with efficacy and compliance. Patients who had only trialled transdermal oxybutynin were included in the assessment of side effects.

## RESULTS

### Patient Demographics:

- 27 patients met inclusion criteria. 18 of had trialled both oral and transdermal formulations. 9 patients trialled only transdermal oxybutynin.
- Cohort had an even gender split (52% males, 48% females).
- The mean patient age was 10 years with a range of 4 to 18.
- The majority of our patients suffered from spina bifida. Other causes of neurogenic bladder included spinal dysraphism, injury, sacral agenesis and transverse myelitis.
- Nearly all included patients used regular catheters (96%). Over 40% of the patients also used adjunctive therapy such as botox and surgical interventions to manage their bladder symptoms.
- At the time of study, most patients were using transdermal oxybutynin. 83% of those that had trialled both formulations were currently using oxybutynin patches and 78% of those that had only trialled patches had ongoing use.

### Efficacy:

Our questionnaires asked patients and carers to report their impression of symptom control with use of both oral and transdermal forms on a scale of 1-5, with 5 being optimal control. Transdermal oxybutynin appeared to have equal or improved efficacy compared to oral medication (3.85 compared to 3.41,  $p < 0.1$ )

### Patient Compliance:

Compliance was reported in terms of ease of use and frequency of missed doses. Transdermal medication was missed less frequently than oral (1.89 compared to 2.59,  $p < 0.05$ ) and was easier to use (4.33 compared to 3.7,  $p < 0.1$ ).

### Patient Preference:

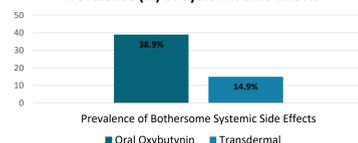
Two thirds of patients preferred use of transdermal patches, reasons cited included ease of use and fewer side effects. Of the third of patients that preferred oral medication, this was due to the patch falling off in addition to skin irritation.

## SIDE EFFECTS

### Systemic side effects:

- Oral medication was associated with increased rates and severity of systemic side effects when compared to transdermal patches.
- 38.9% of those taking oral medication reported systemic side effects as at least 'somewhat bothersome' on self-reported scale. 14.8% of those using patches reported systemic side effects of the same severity.
- For those using oral medication, the most commonly reported side effects were dry mouth, headaches and drowsiness.

Graph 4: Patient/Carer Reported Prevalence (%) of Systemic Side Effects



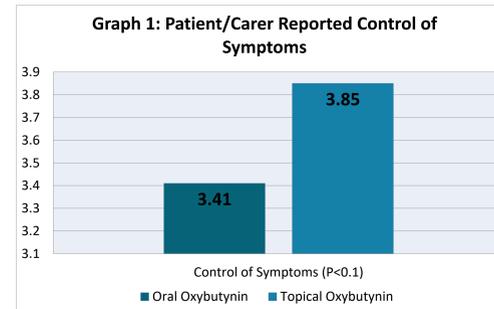
Graph 4: Prevalence of Systemic Side Effects

Rates of self/carers reported systemic side effects scoring 3 or greater.

Patient/Carer Questionnaire:  
How much were you bothered by this side effect:  
Not at all (1)  
A little (2)  
Somewhat (3)  
Very (4)  
Extremely (5)

### Local side effects:

The most commonly reported side effects of transdermal oxybutynin were local side effects such as redness and itch at the application site. Just over a quarter of patients reported local side effects that were at least 'somewhat' bothersome.



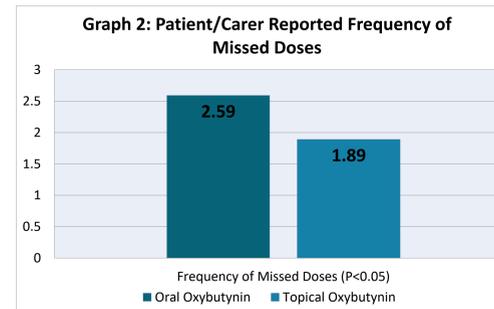
### EFFICACY

Graph 1: Control of Symptoms

Patient or carer reported efficacy of control of symptoms with oral versus transdermal formulation. Symptom control was rated on a scale of 1-5

Patient/Carer Questionnaire:  
How did you/your child feel taking this medication regarding continence control?

- Very poor control (1)
- Poor control (2)
- Average control (3)
- Good control (4)
- Very good control (5)

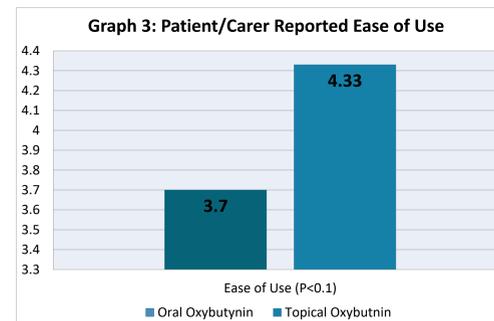


### COMPLIANCE

Graph 2: Frequency of Missed Doses

Patient or carer reported compliance was assessed using self-reported frequency of missed doses with each formulation, rated on a scale of 1-5.

Patient/Carer Questionnaire:  
How often were doses missed?  
Less than once a month (1)  
Once or twice a month (2)  
Once a week (3)  
More than once a week (4)  
Almost every day/every day (5)



### COMPLIANCE

Graph 3: Ease of Use

Patient/carers reported ease of use of oral versus transdermal Oxybutynin was assessed on a self-reported scale of 1-5.

Patient/Carer Questionnaire:  
How easy was it to get your child to take oxybutynin?  
Very difficult (1)  
Difficult (2)  
Not particularly difficult (3)  
Easy (4)  
Very easy (5)

Table 1: Patient Formulation Preference

	Transdermal Formulation	Oral Formulation
Patient Preference	12 (66.6%)	6 (33.3%)
Reason for preference	<ul style="list-style-type: none"> <li>Ease of use (50%)</li> <li>Fewer side effects (41.7%)</li> </ul>	<ul style="list-style-type: none"> <li>Patch falling off (50%)</li> <li>Skin irritation (33.3%)</li> </ul>

## CONCLUSIONS

- The majority of pediatric patients in our cohort preferred transdermal patches when compared to oral formulations of oxybutynin.
- Patches were preferred due to ease of use and reduced systemic side effects.
- Transdermal oxybutynin had improved patient/carers-reported efficacy and compliance.
- Systemic side-effects are common with oral formulations, in particular dry mouth, drowsiness and headaches.
- The most significant limiting factors for oxybutynin patches are local side effects such as skin irritation and the patch falling off.
- The data suggests that transdermal oxybutynin is a good alternative to oral medication in children with neurogenic bladder.

## ACKNOWLEDGEMENTS

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