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CAN TRANSDERMAL OXYBUTYNIN PATCHES REDUCE THE NEED FOR INTRAVESICAL BOTOX INJECTIONS?

Hypothesis / aims of study

The Overactive Bladder (OAB) syndrome is a distressing condition that is common and is reported to affect up to 20% of the population in European countries. The condition usually responds to conservative treatment with bladder retraining, and also to complementary therapies such as acupuncture, hypnotherapy and reflexology. However the mainstay of medical management is pharmacological using anticholinergic drugs, which generally help up to 90% of sufferers. A dilemma therefore exists how to treat those individuals who are refractory to drug therapy: major surgical reconstruction operations such as clam enterocystoplasty and detrusor myomectomy have been advocated but they have a high morbitity associated with them. Although unlicensed, intravesical Botox injections are frequently used in refractory cases to oral anticholinergics before resorting to more major surgery. Oxybutynin is a well-established drug used in the management of OAB. It has been available in tablet form for many years and is effective at doses up to 15mg daily but its use is limited by its side effect profile, especially dry mouth, dry eyes and constipation, which are characteristic of all anticholinergic drugs. A transdermal preparation of oxybutynin (Kentera) has therefore been recently released which attempts to reduce these side effects and maintains a higher and more stable serum level of active drug. This study was therefore carried out to ascertain the beneficial effects of Kentera in women suffering from refractory OAB and whether the improvement was sufficient to avoid the use of intravesical botox injections.

Study design, materials and methods

29 non-neuropathic women were recruited into the study: all the women had undergone bladder retraining and a failed trial of oral anticholinergic medication. In our unit, the initial oral anticholinergic drug used is proprietary oxybutynin, followed if unsuccessful by slow release oxybutynin and then a more modern anticholinergic such as Solifenacin, Tolterodine or Trospium Chloride. Women treated unsuccesfully are then offered an intravesical botox injection. Before treatment with Kentera, an Incontinence Quality of Life questionnaire (I-QoL) was completed: this is a validated 22 question survey looking at all aspects of incontinence, and to each question there are 6 answers ranging in impact which can be scored and subjective improvement calculated and compared between individuals. In addition a Patient Perception of Intensity of Urgency Scale (PPIUS) was carried out: this is a validated scale from 0 to 4 with the number increasing with severity of urgency. A Perception of Bladder Condition (PBC) score was also carried out: in this assessment, the women ticked 1 of 6 boxes as to how much their bladder problem affected them. The perception gradually increases and therefore we applied a scale 1 to 6 so these results could be subjectively quantified. Transdermal Kentera giving a daily dose of 3.9mg of oxybutynin was then used for up to 3 months, and the women were then reviewed where the same questionnaires were completed. In addition a visual analogue scale (VAS) of treatment satisfaction ranging from 0 to 10 was carried out in addition. Both parametric (T-Test) and non-parametric tests (Mann-Whitney) were used to determine statistical significance.

Results

All 29 women completed the questionnaires pre treatment with Kentera and attended for follow up. 5 women failed to complete the 3 month course and discontinued from the study: in 3 women this was due to unbearable persistence of anticholinergic side effects and in 2 women due to severe skin irritation at the application site. The VAS satisfaction of treatment ranged from 1 to 10 (mean 4.6409: median 4.9500). The results of the other questionnaires are shown in the table below:

	Pre		Post		T-Test	Mann-Whitney
	Mean	Median	Mean	Median	p value	p value
1	1.45	1.00	1.77	2.00	0.1700	0.2272
2	3.17	3.00	3.41	4.00	1.6000	0.5555
3	2.72	3.00	3.18	4.00	0.2500	0.2421
4	1.59	1.00	1.86	1.50	0.3600	0.4936
5	2.03	2.00	2.41	2.00	0.2300	0.2199
6	2.07	2.00	2.64	2.50	0.0860	0.0905
7	1.90	2.00	2.36	2.00	0.1800	0.3765
8	2.45	2.00	2.64	2.00	0.4300	0.6687
9	2.00	2.00	2.36	2.00	0.3100	0.3868
10	1.31	1.00	2.05	2.00	0.0089	0.0198
11	2.00	2.00	2.41	2.00	0.2500	0.2956
12	1.57	1.00	1.95	1.00	0.2500	0.3714
13	1.79	1.00	2.32	2.00	0.1300	0.1354
14	2.07	1.00	2.18	2.00	0.3000	0.6076
15	2.93	3.00	3.18	3.00	0.6500	0.4816
16	2.62	2.00	2.95	3.00	0.8200	0.4189
17	2.21	2.00	2.68	3.00	0.1600	0.1650
18	1.62	1.00	2.05	1.00	0.2100	0.3921
19	1.48	1.00	1.95	1.00	0.1100	0.1709
20	1.76	2.00	2.18	2.00	0.1600	0.2129
21	2.52	2.00	2.82	3.00	0.4100	0.3974
22	2.63	3.00	3.05	3.00	0.3500	0.3660
PBC	4.93	5.00	4.45	4.00	0.1000	0.1510
PPIUS	3.52	4.00	2.73	2.50	0.0093	0.0242

Of the 24 women who completed the study, 13 felt their symptoms had not improved sufficiently and therefore went on to have an intravesical botox injection together with the 5 treatment failures. Of the 11 women who did not have a botox injection, 7 felt their symptoms were under control with transdermal oxybutynin patches whilst 4 declined any further treatment.

Interpretation of results

These results show that I-QoL scores are not improved overall by the application of transdermal oxybutynin patches. Only 1 domain (question no 10: " It's important for me to be able to make frequent trips to the toilet") reaches statistical significance. There is no overall improvement in perception of bladder condition but urgency scores are improved, which is perhaps related to question number 10.

Concluding message

In conclusion, this study shows that transdermal oxybutynin patches do not appear to have a major impact in reducing rates of intravesical botox injections for refractory OAB. However this cohort of women studied are the worst-case scenarios who are likely to be resistant to most treatment modalities. We would concur with previous studies, which have shown transdermal oxybutynin to be effective for OAB symptoms when used as first line treatment especially for poor compliers, but we cannot advocate it routinely for refractory OAB to avoid the need for further surgery.

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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Torbay Local Research Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**