893

Tincello D[1], Kenyon S[2], Slack M[1]
***1.** University of Leiceter, **2.** University of Birmingham*

BOTULINUM NEUROTOXIN A FOR DETRUSOR OVERACTIVITY: QUESTIONNAIRE SURVEY OF CURRENT UK PRACTICE AMONG GYNAECOLOGISTS AND UROGYNAECOLOGISTS

Hypothesis / aims of study

Botulinum toxin A (BoNT-A) is rapidly developing as an attractive treatment option for refractory idiopathic detrusor overactivity in men and women. Robust longterm controlled data on its use are still lacking, and the National Institute for Clinical Excellence in the UK and other organisations recommend it should only be used in the research setting(1,2). The drug still does not have a license for this indication in either the USA or Europe.

In the UK, the availability of BoNT-A as a treatment is highly variable and many gynaecologists do not offer the treatment. This survey study was conducted to determine the availability of BoNT-A treatment as provided by UK gynaecologists and also to obtain the views of these clinicians about the reasons for availability, method of administration and criteria for selecting patients.

Study design, materials and methods

An online questionnaire was developed using SurveyMonkey. Questions addressing use and availability of BoNT-A, reasons for use or non-use, and criteria for patient selection were included. This was piloted on members of the research subcommittee of the British Society of Urogynaecology and the investigators on a large UK based randomised trial of botulinum toxin(*). Following revision, this was mailed electronically to the entire membership of the British Society of Urogynaecology (302). A reminder email was sent four weeks later.

Responses were downloaded from the SurveyMonkey website, and entered into SPSS v16 for analysis. Results are presented as number (%), with 95% confidence intervals (CI) of percentage differences. Comparisons between groups were done by Chi square, with Yates' correction if necessary on small numbers.

Results

105 (35%) responses were received, 66 (63%) from urogynaecologists and 39 (39%) from general gynaecologists with a special interest. All but 12 were consultants, so the remaining analyses are presented on the 93 responses from consultants. Overall, 51 consultants (55%) were offering BoNT-A, but more urogynaecologists (66%) than generalists (35%) were offering treatment (difference 30.8%; 95%CI 9.8, 51.8). 36 (70%) of those offering treatment used BOTOX (Allergan), most often 200u; 9 (18%) used Dysport (Ipsen), most often 500u, with the other 6 (12%) using either preparation or being unsure which was used.

One quarter of clinicians offering BoNT-A felt there was conclusive evidence in favour, and almost three quarters believed it to be of benefit (Table 1), with more urogynaecologists (51%) than generalists (29%) believing this (difference 21.4; 95% CI 0.5, 42.3) (Table 2). 31 (42%) of the 42 clinicians not offering BoNT-A treatment reported lack of funding as the reason, and 9 (29%) said the evidence was not conclusive. Reported criteria for treatment with BoNT-A are shown in Table 3, and method of administration in Table 4.

Table 1- Evidence in support of BoNT-A by availability

Why do you treat with BoNT-A?	BoNT-A offered?		p
	No (n=42)	Yes (n=51)	
There is conclusive evidence of benefit for BoNT-A	1 (2%)	13 (25%)	0.002
I believe BoNT-A to be of benefit	4 (4%)	36 (71%)	<0.0001
There is National Policy or Guideline available	0	9 (18%)	0.004

Table 2- Evidence in support of BoNT-A by specialty

Why do you treat with BoNT-A?	Specialty		p
	Gynaecology (n=34)	Urogynaecology (n=59)	
There is conclusive evidence of benefit for BoNT-A	3 (9%)	11 (19%)	0.202
I believe BoNT-A to be of benefit	10 (29%)	30 (51%)	0.044
There is National Policy or Guideline available	1 (3%)	9 (14%)	0.095

Table 3- Criteria for treatment (51 responses)

	Always	Sometimes	Never or n/a
Only treat cases with confirmed DO	43	6	1
Treat patients with OAB symptoms	4	6	32
Treat after trial of one drug	1	6	33
Treat after trial of two drugs	13	18	13
Treat after three or more drugs	29	9	5
Patient must Learn ISC before treatment	33	13	3

Table 4- Method of administration (51 responses)

	Always	Sometimes	Never or n/a

Flexible cystoscopy under local anaesthetic	10	12	16
Flexible cystoscopy under general/regional anaesthetic	0	10	22
Rigid cystoscopy under local anaesthetic	2	10	24
Rigid cystoscopy under general/regional anaesthetic	18	16	9
One dose of prophylactic antibiotics	22	8	14
More than one dose of antibiotics	7	8	17

Interpretation of results

This survey is the first to provide a snapshot of the patterns of BoNT-A use among gynaecologists and urogynaecologists in the UK. BoNT-A was provided by half the respondents, with more urogynaecologists providing treatment. The majority of respondents were aware of the perceived benefits of BoNT-A while being aware of the lack of conclusive evidence in favour of it. The most common reason for not providing treatment was lack of funding.

The majority of clinicians would treat only patients with confirmed detrusor overactivity (DO), and after two or three trials of anticholinergics, and the majority would prefer women to learn to self catheterise before treatment.

Concluding message

Availability of BoNT-A treatment by UK gynaecologists is variable, and seems to be influenced by subspeciality practice. Funding appears to be major issue hindering provision of this potentially effective treatment, although some clinicians may be reluctant until good quality longterm evidence of efficacy is provided. The situation in other healthcare delivery systems (i.e. those where healthcare is not funded by Government) may be different.

References

1. National Institute for Health & Clinical Excellence. Urinary incontinence: costing report - implementing NICE guidance in England. Clinical guideline CG40. 2006. London. National Institute for Health and Clinical Excellence
2. Apostolidis A, Dasgupta P, Denys P et al. Recommendations on the use of botulinum toxin in the treatment of lower urinary tract disorders and pelvic floor dysfunctions: a European Consensus Report. Eur Urol 2009;55:100-120.

Specify source of funding or grant	**Funded by grants from The Moulton Charitable Trust and Wellbeing of Women**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**It was a postal survey of clinicians, not patients and was approved by the research subcommittee of the British Society of Urogynaecology.**
Was the Declaration of Helsinki followed?	**No**
This study did not follow the Declaration of Helsinki in the sense that	**There was no intervention upon patients,and there was no risk of harm to participants.**
Was informed consent obtained from the patients?	**No**