Intravesicle Injection of Botulinum A Toxin for the Treatment of Overactive Bladder in Anticoagulated Patients – Is it Safe?

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Introduction

Botulinum Toxin A (BoNT-A) proved effective minimally invasive treatment of overactive bladder (OAB) refractory to medical therapies.

Since its licensing by the Medicines and Healthcare Products Regulatory Agency (MHRA) in Sept 2012 there has not been a formal guideline produced to aid surgeons in the management of patients receiving concomitant antiplatelet or anticoagulant therapy.

Although Intravesical BoNT-A injections are carried out in clinics and regularly performed under local anaesthetic there still exists reports of treatment-related significant adverse events (SAE) (20%–43%). Acute urinary retention (AUR), large post-void residual (PVR) requiring clean intermittent self-catheterisation (CISC) and urinary tract infection (UTI) are common SAEs.

Haematuria is a well-documented and common risk with urinary tract procedures however; there is a lack of evidence quantifying type, duration and severity. In studies claim rates of 3.6-5.2% of total patients experience haematuria however up to 21% in another– this may be concerning in patients who are anticoagulated.

Currently there are no studies or guidelines published regarding the concomitant use of both anticoagulant therapies and intravesical use of BoNT-A. Due to the theoretical risk of bleeding patients taking anticoagualnts were either excluded from trials or had their anticoagulants ceased one week prior to procedure.

Aim

The aim of this single centre retrospective study is to explore potential significant adverse effects (SAE) of intravesical BoNT-A with concomitant anti-platelet and/or anticoagulation therapy.

Method

Patients were identified from Morriston Hospital Urology Department intravesical BoNT-A procedural lists using name and hospital identification number between January 2013 to December 2016 (4 years).

A standard proforma was used and applied to all procedural encounters. Data was obtained from electronic medical records (operation notes, discharge summaries, clinic letters and medication records).

Data was analysed by the Morriston clinical audit department. Significant Adverse Effects were classified as follows: Gross haematuria (lasting more than 72 hours/ requiring medical attention), AUR/ PVR >150ml requiring CISC, UTI, Failure of treatment, Weakness, Allergic reaction

Results

Total of 353 procedures carried out over a 4 year period. Mean age 60.7 years old (range 22-91) Male = 75 Female = 278. 19.3% were receiving antiplatelet (AP) or anticoagulant (AC) therapy (68/353).

SAE was reported in 2.8% of patients not receiving AP/AC therapy (8/285). 5.9% of the patients who were on AP/AC therapy (4/68) had significant post-procedure haematuria (2 on

aspirin and 2 on warfarin). 14 patient deaths during data collection period – none attributed to intravesical injection of BoNT-A.

Conclusions

Cystoscopy and intravesical injection can be classed as low-risk for haemorrhage. To our knowledge, we believe this study to be the first to specifically look in to the incidence of haematuria post intravesical BoNT-A injection. In our 4-year retrospectively collected data, the risk of haematuria was relatively low (5.9%).

The risk of stopping a patient's anticoagulant pre-operatively has, to date, been assessed on a case-by-case basis due to a lack of evidence in the literature. Considerations must not only be given to pre-operative cessation of anticoagulation but also to requirements of bridging therapy and recommencement of anticoagulation post operatively.

The decision to discontinue antiplatelet/ anticoagulant therapy is subject to local guidance and risk/ benefit consideration for the individual patient. Those patients on anti-coagulation therapy need to be managed appropriately to decrease the chance of bleeding.

A wider discussion regarding local policy nationally would be encouraged with other centres participating in further retrospective/ prospective data analysis to assess the risk of continuing or withholding AP/AC medications in those patients undergoing intravesical BoNT-A therapy. This will aid formulation of guidelines to identify at-risk patients and help in managing their anticoagulation status pre-operatively