INAHTA Brief

## Title Botuli num Toxin Type A (BTA) Injection for Chronic Anal Fissure (CAF)

AgencyHTA Malaysia, Health Technology Assessment Section, Medical Development Division, Ministry of Health Malaysia<br/>Level 4, Block E1, Parcel E, Presint 1,<br/>Federal Government Administrative Center, 62590 Putrajaya, Malaysia<br/>Tel:+603 88831229, Fax:+603 88831230; www.moh.gov.my

# *Reference* Technology Review Report - 005/2018, online:

http://www.moh.gov.my/index.php/database\_stores/store\_view\_page/30/322

## Aim

To assess the safety, efficacy or effectiveness and costeffectiveness of BTA injection for CAF

#### **Conclusions and results**

The included studies consisted of three systematic review (SR) and meta-analyses, one SR and network meta-analysis, one SR, five pre- and post- intervention studies, one non-randomised controlled trial, and one cost analysis study.

Effectiveness:

- Combination of BTA and fissurectomy for CAF showed an improvement in CAF
- Lateral internal sphincterotomy (LIS) surgery was more effective in healing and preventing recurrence of anal fissure compared with BTA but incontinence was lesser with BTA compared with LIS
- There was no significant difference in healing, recurrence rate and incontinence rate among BTA injection and topical nitrates
- BTA injection was significantly more effective than lidocaine
- Different doses of BTA, different injection sites and different types of BTA formulation, did not significantly affect the efficacy and effectiveness of BTA injection for CAF treatment

#### Safety:

- Common complication in the combination treatment was anal bleeding that resolved spontaneously few days after treatment
- Other reported complications that occurred after combination treatment were perianal sepsis, recurrence anal fissure, pruritus ani, delayed healing, and headache
- Comparing BTA injection with topical nitrates, there was more significant complications especially headache occurred in topical nitrates group compared to BTA injection
- The systematic reviews reported BTA injection had low frequencies of adverse events which were mostly local post-operative complications such as hematoma, perianal thrombosis, perianal abscess and temporary incontinence that consisted of liquid and faeces
- One case of fourniere gangrene was reported in patient with diabetes mellitus
- Contraindications included hypersensitivity case, pregnancy, neurological disease including myasthenia,

may enhanced the action of BTA

Cost/cost-effectiveness:

• No local cost analysis was retrieved on the management of CAF with BTA injection

Lambert Eaton Syndrome and Amyotrophic lateral

sclerosis and co-administration with a mino-glycosides

 One cost analysis from United State of America showed that combination of treatment (BTA injection and surgery for any fail BTA case) was cost saving compared to only surgery (LIS) approach

Organizational:

- BTA injection is not standard practice for CAF in Ministry of Health Facility
- BTA injection is not registered for CAF

### Recommendations

Botulinum toxin type Ainjection for chronic anal fissure is recommended for selective patients

#### Methods

Electronic databases were searched through Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1948 to present, EBM Reviews-Cochrane Database of Systematic review, EBM Reviews-Cochrane Methodology Register of Controlled Trials, EBM Reviews-Health Technology Assessment, EBM Reviews-NHS Economic Evaluation Database, and Embase 1996 to 18 Jun 2018. Searches were also run in PubMed, FDA website and INAHTA for any published reports.

No limit in the study year. Google and Google Scholar were also used to search for additional web-based materials and information about the technology. Besides, additional articles were also search by reviewing the references of retrieval articles.

#### Further research/reviews required

Further research especially local research is required for further assessment on the safety and effectiveness as well as cost-effectiveness of BTA injection for CAF before it can be widely used in Ministry of Health.

#### Written by

Maharita Ab Rahman, MaHTAS, Malaysia