

The AqueSys Xen® Gel Stent

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Introduction: The term 'glaucoma' refers to a group of eye diseases that cause damage to the optic nerve, generally due to increased intraocular pressure (IOP). Treatment is based on reducing the IOP. The primary treatments consist of topical medication in the form of eye drops and/or Selective Laser Trabeculoplasty (SLT): if these do not work, or if there is any intolerance to the medication, surgery is used. In general, the surgery of choice is trabeculectomy; however, in an attempt to reduce the frequency of the associated complications, safer and equally effective alternatives are sought, such as incisional or micro-incisional glaucoma surgery (MIGS). The latter group include the AqueSys XEN-45® implant.

Aims: To evaluate by means of a systematic review the AqueSys XEN-45® implant for the treatment of primary open angle glaucoma (POAG) with regard to its effectiveness and safety in comparison to the standard therapy (trabeculectomy). The variables evaluated were changes in the IOP and the reduction of drugs required to control the pressure.

Methods: A review was carried out of the scientific literature until 2018 in the following databases specialising in evaluation reports and reviews (HTA (CRD database), INAHTA and Cochrane), in general databases (Medline (PubMed), Embase (Ovid SP) or ISI), and a search of databases from research projects that are currently underway (Clinicaltrials.gov). Two reviewers independently read and selected the articles based on previously defined selection criteria. This information was summarised in evidence tables.

Results: The bibliographic search provided 198 articles, out of which the full texts of 18 were read, selecting 6 for inclusion in this study. Five of them, included for the safety-effectiveness analysis, are studies of case series without a comparison group, with a short follow-up period and a small number of patients. The other study that was included was a questionnaire presented to Canadian professionals who carry out the technique in order to analyse its learning curve. The results obtained in the studies were homogeneous and reflect a significant reduction both of the IOP and number of topical drugs administered, also indicating a high safety margin with few short-term side effects.

Conclusions: The AqueSys XEN-45® implant reduces IOP and the number of topical drugs required. The procedure proved to be safe, with a low number of side effects. However, few studies have been carried out and the level of evidence is low, meaning results are necessary from randomised clinical trials or multi-centre comparison studies with a larger number of patients.