

Original research article

Increasing trends in the use of the Precivia® intravitreal injection assist device across the UK

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Background Intravitreal anti-VEGF injections are the most frequently performed outpatient procedure in the UK, the need for which continues to rise. To meet this demand, injection assist devices such as Precivia® are increasingly adopted to aid in their prompt and safe delivery. We present data on the usage of Precivia® intravitreal injection assist device across two district general hospitals and its distribution across the UK over five years.

Methods A retrospective review was undertaken of all Precivia® assisted intravitreal injections delivered at Great Western Hospitals NHS Trust (GWH), and Gloucestershire and Cheltenham Hospitals NHS Trust (GCH) between 2015–2020. Data were also obtained from the Precivia® device UK distributor; Veni Vidi Medical.

Results In GCH, 47,968 intravitreal injections were administered with Precivia®: 5947 in year 1; 7058 in year 2; 9893 in year 3; 11,503 in year 4 and 13,567 injections in year 5, observing a 128.13% increase in the use of Precivia® over the five-year-period. In GWH, 26,923 injections were administered with Precivia®: 4232 in year 1; 5117 in year 2; 5437 in year 3; 5878 in year 4 and 6259 in year 5, observing a 47.89% increase in Precivia® injections over a five-year study period. The number of Precivia® devices distributed across the UK similarly increased including 42,150 devices sold in 2015; 68,125 in 2016; 72,575 in 2017; 88,325 in 2018; 112,850 in 2019 and 115,125 in 2020 observing a 173.31% increase in five years.

Conclusion An increasing trend in the use of the Precivia® intravitreal injection assist device was observed across the UK.

Keywords

Anti-VEGF, intravitreal injections, nurses, service delivery, safety, retina.

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Summary statement

The demand for intravitreal anti-VEGF injections has significantly increased over recent years. We demonstrate an incremental increase in the uptake of the Precivia® intravitreal injection assist device across two large district general hospitals and the number of devices distributed across the UK to meet this demand. This growing popularity may prompt an increasing trend of the same or similar injection assist devices, shifting away from more traditional injections methods.

Introduction

Over the last decade, intravitreal injections of anti-Vascular Endothelial Growth Factors (anti-VEGF) have increased.¹ Anti-VEGF injections are first-line treatment for retinal pathologies such as neovascular age-related macular degeneration (nAMD).¹ The demand for anti-VEGF injections has significantly increased since the National Institute for Health and Clinical Excellence (NICE) approved ranibizumab for the treatment of nAMD in August 2008.² The Royal College of Ophthalmologists has recommended training allied health professionals, such as ophthalmic nurses and technicians, to deliver this service under supervision by ophthalmologists. Ophthalmic departments across the UK have demonstrated this to work safely and successfully.^{3,4}

The development of intravitreal injection assist devices enables the delivery of this service and exponential demand. The Precivia® (née Invitria®) (FCI Ophthalmics, USA) intravitreal injection assist device has been adopted into clinical practice.^{3,5} The **single-use** device is placed 3.5 mm from the limbus with a central aperture to ensure globe fixation. It has a circumferential flange to splay lashes from the injection site and enable suitable lid retraction (Figure 1). A 28° angled guided port allows the injection of anti-VEGF with a 30-gauge needle at a fixed depth of 5.6 mm in a consistent and repeatable manner. Precivia® device is also useful for patients with difficult positioning as injectors can safely administer injections with patients seated or semi-recumbent, ensuring patient comfort. Traditional practices for delivery of intravitreal injections include drape and speculum, which can be more time-consuming and technically challenging in some cases.^{5,6}

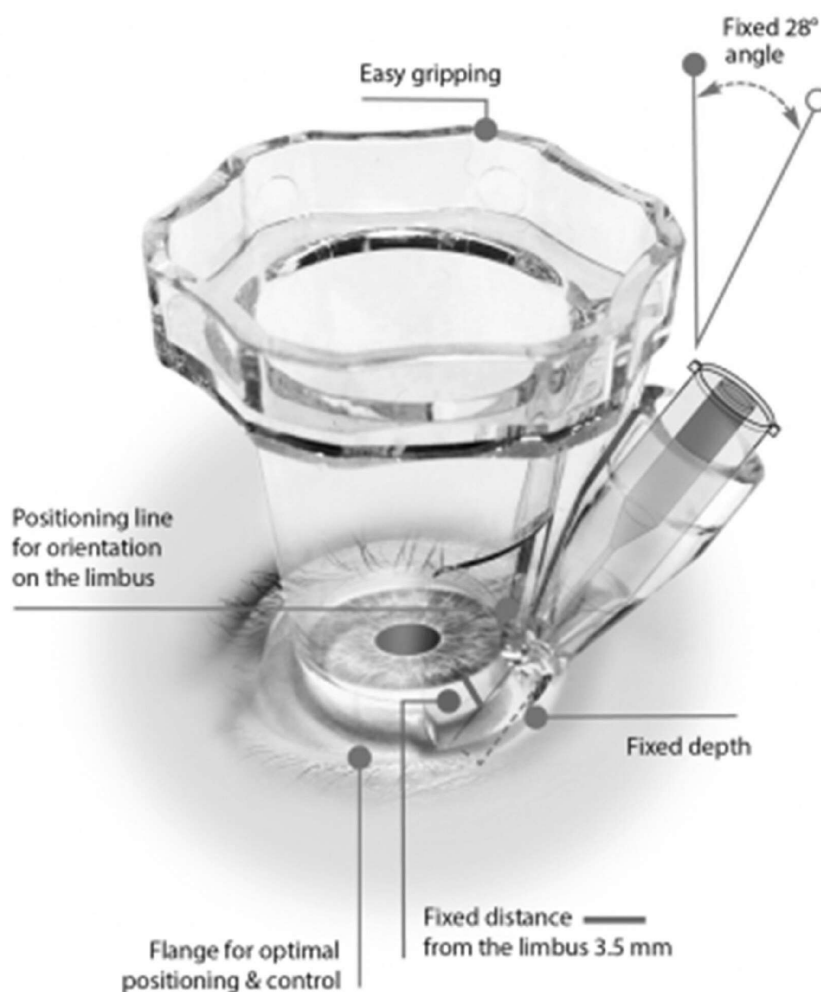


Figure 1. Schematic representation of the Precivia® intravitreal injection assist device.

We have previously published data on the safety and efficacy profile of the Precivia® device in a nurse-led intravitreal injection service. We reported a low rate of endophthalmitis (0.015%) over five years and no cases of lens touch or retinal detachment.³

In this study, we present data on the usage of the Precivia® intravitreal injection assist device across two district general hospitals and its distribution across the UK over five years.

Materials and methods

Data collection

Retrospective data collection were obtained from injection clinics at two UK NHS Hospital Trusts from 2015 to 2020, namely Great Western Hospitals NHS Trust (GWH), and Gloucestershire and Cheltenham Hospitals NHS Trust (GCH). Data including number of intravitreal injections undertaken at each site per year and collated from Medisoft electronic patient records (Leeds, UK). The number of devices distributed annually across the UK from 2015 to 2020 were provided by Veni Vidi Medical (Halifax, UK), the UK's distributor for the Precivia® device.

Inclusion criteria consisted of all patients who received intravitreal anti-VEGF injections for any relevant retinal pathology. Excluded patients were:

- Patients with previous history of trabeculectomy
- Patients with previous history of keratoplasty
- Recent cataract surgery (within 4 weeks)

Any of the above excluded patients were reallocated for an ophthalmologist to perform the injection and removed from the dataset.

Intravitreal injection procedure

5% povidone-iodine solution is used to achieve periocular antisepsis. Topical anaesthetic e.g., proxymetacaine hydrochloride (0.5% w/v) is instilled. The Precivia® device is then carefully positioned onto the limbus, ensuring its flanges avoid contact with the eyelashes. Gentle pressure is applied to enhance an anaesthetic effect and the device is rotated to displace the conjunctiva. A 30-gauge needle is guided through the injection port at a fixed angle and depth. Once injected, the needle is withdrawn and the device is rotated to replace the conjunctiva and occlude the injection site. The instrument features a 'paracentesis window' to facilitate swift access to perform a paracentesis if required.

Results

In GWH, 26,923 intravitreal injections were administered with the Precivia® injection assist device over the five-year-period (see Figure 2). An incremental increase in the number of injections was observed each year: In year 1, 4232 injections; year 2, 5117 injections; year 3, 5437 injections; year 4, 5878 injections and in year 5, 6259 injections. A 47.90% increase in the use of Precivia®-assisted injections was observed over the five-year-period.

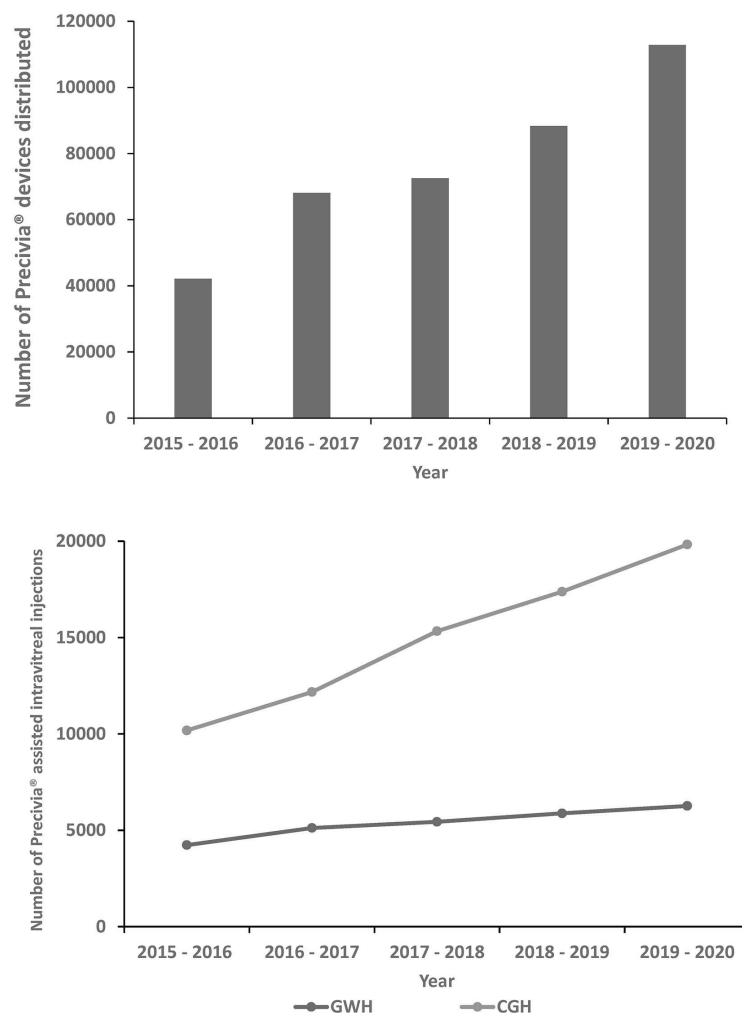


Figure 2. Top panel details the number of Precivia® devices distributed across the UK. The bottom panel demonstrates the number of Precivia®-assisted intravitreal injections delivered in two NHS hospital trusts.

In GCH, 47,968 intravitreal injections were administered with the Precivia® injection assist device over the five-year-period (see Figure 2). An incremental increase in the number of injections was also observed each successive year: In year 1, 5,947 injections; year 2, 7,058 injections; year 3, 9,893 injections; year 4, 11,503 injections and in year 5, 13,567 injections. A 128.13% increase in the use of Precivia®-assisted injections was observed over the five-year-period.

The number of Precivia® devices distributed across the UK similarly increased over five years. 42,150 devices were sold in 2015; 68,125 in 2016; 72,575 in 2017; 88,325 in 2018; 112,850 in 2019 and 115,125 in 2020, observing a 173.31% increase in five years (see Figure 2).

Discussion

The study demonstrates a significant uptake of Precivia®-assisted intravitreal injections across two NHS hospital sites. An increasing trend in its distribution across the UK over five years suggests the device is gaining nationwide popularity.

We have previously demonstrated the safety and efficacy profile of Precivia® devices in a nurse-led injections service.⁶ 20,421 injections were delivered at GWH over five years with Precivia® with an endophthalmitis rate of 0.015%,³ comparable with the published benchmark rates by the Royal College of Ophthalmologists (this data included injections delivered with all modalities).^{5–8} All relevant pathologies necessitating anti-VEGF therapies were included in our cohorts; this extended beyond nAMD to include clinically significant macular oedema associated with diabetes; retinal vascular occlusive disease; retinal angiomatous proliferations; myopic and peripapillary choroidal neovascular membranes. This is especially

important as prevalence of such conditions, particularly nAMD and diabetic macular oedema, are increasing and such patients may benefit from anti-VEGF therapy.⁹ Moreso, with nAMD being treated earlier in patients with better visual acuity, this will further the burden on intravitreal injection services. It is therefore critical for healthcare providers to predict and prepare for such demands.

We found the devices speed and ease of usage enabled a higher turnover of injections than when compared with traditional methods of surgical draping and lid speculum. A prospective review by Ratnarajan et al. demonstrated that this injection-assist device eliminated the cost of additional apparatus that comes in a traditional pack: a surgical drape, lid speculum, callipers, disposable Moorfields forceps, two gallipots, gauze and gauze holders, tray cover and needle disposal block, resulting in a saving of £7.70 per patient.¹⁰

The advantage of this device is that it standardises needle position, depth and angle while maintaining patient fixation and lid retraction, thereby maintaining consistent and repeatable injections. Limitations of the Precivia® device include its transparent polycarbonate material which some patients have stated they are able to visualise the needle as it is approaching the globe, and this can contribute to patient anxiety and/or pain. Hence, gentle pressure with the device is applied when injecting to enhance anaesthesia.

In a previous study, the authors have demonstrated how we created a successful nurse-led injection service through developing a structured nurse training programme.¹¹ Ophthalmic nurses enrolled in a 12-week training programme to achieve competency in delivering intravitreal injections independently using the Precivia® device, with a trained ophthalmologist available on site.¹¹ Training consisted of a theory course detailing eye anatomy, pathology of nAMD and the therapeutic effect of anti-VEGF injections.¹¹ Outcomes were then assessed through a theory test of 50 single best-answer questions. Subsequently, nurses observed a clinician-led injection clinic for two weeks before performing 50 injections under supervision.¹¹ Over the 12 weeks, nurses went from observation to safe, independent service provision. A previous survey has shown a high level of patient satisfaction in the nurse-led service.¹² In our experience, trainee ophthalmologists also achieved competency quickly delivering injections when using Precivia®.

Other intravitreal injection assist devices are available on the market to address the high injection burden. Waqar et al used the Malosa Intravitreal Injection Guide (Beaver-Visitec International, Waltham, MA) consisting of a sterile, single-use, polycarbonate instrument consisting of a lash guard, a curved footplate with 3 fixation studs and a cylindrical needle chamber.¹³ The Rapid Access Vitreal Injection (RAVI) Guide (Katalyst Surgical, Chesterfield, MO) is another autoclavable, titanium device comprising of a square baseplate with a central 1.5 mm aperture to facilitate intravitreal injection which also eliminates the need for a drape and speculum.¹⁴ The authors here compared the RAVI device with surgical draping and lid speculum method with respect to a pain-scoring system and found no significant difference between the two in a small, 54 patient prospective study.¹³ The SP.eye® (Safety Precision) is one-piece device which incorporates a 30-gauge intravitreal needle with a plastic, guiding footplate and calliper. In addition, it was designed as a first of its kind to avoid needlestick injuries after injections by integrating a sharps-safe system so the device can be locked safely immediately after use, however users found it to be bulky and cumbersome limiting the devices' overall uptake.¹⁵ To the best of our knowledge and to date, there are no large-scale studies assessing the safety and efficacy of these devices therefore further studies may be warranted. Other alternative injection-assist devices of limited popularity are also obtainable on the market but is beyond the scope of this paper.

Despite this study's retrospective design, a large sample size shows a clear increasing trend in the use of Precivia® nationwide. Furthermore, although a nationwide 173.31% increase in device distribution over a five-year period was seen, this does not necessarily equate to a similar uptake across the two sites in the present study (see Figure 2). This may be due to potential wastage of the device, or variables in patient demographics between sites with more high-risk patients that Precivia® is unsuitable for. However, an incremental increase in its usage over five years suggests increasing popularity for this device.

Conclusion

An increasing trend in the use of the Precivia® intravitreal injection assist device was observed in two district general hospitals along with an increase in the number of devices sold across the UK over a five-year period, from 2015–2020. An increasing body of evidence demonstrates its safety, efficacy, ease of use and cost-effectiveness. Further studies are warranted to compare other intravitreal injection assist devices and assess their clinical performance with Precivia®.

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