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Safety and efficacy of nurse led intravitreal injection service with Precivia® injection assist device

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Abstract

Introduction: Intravitreal anti-VEGF injections are the most frequently performed outpatient procedure in the UK. Ophthalmic allied healthcare professionals are replacing medical professionals in delivering injections nationwide. The use of injection assist devices such as Precivia® has been well established and increasingly adopted to aid in their safe delivery. We present outcomes of nurse-led intravitreal injections using the Precivia® injection assist device over a five-year period in the UK.

Methods: A retrospective review was completed of all anti-VEGF intravitreal injections delivered at the Great Western Hospital between May 2015 and May 2020.

Results: Over the five-year study period, 2318 patients underwent a total of 26,923 intravitreal injections; 20,421 (75.8%) of which were delivered by appropriately trained ophthalmic nurses. The annual number of injections increased year-on-year from 2112 injections in 2015-2016 to 5410 injections in 2019-2020. The mean age of patients was 75.7±12.2 years with a female-to-male ratio was 1.17:1. Wet age-related macular degeneration represented the major indication for injections followed by retinal vein occlusion and diabetic maculopathy respectively. Three cases of post-injection endophthalmitis out of 20,421 (0.015%) injections in nurse injection group were identified during the study period. There were no cases of lens touch, retinal detachment or systemic thromboembolic events.

Conclusion: Use of the Precivia® intravitreal injection assist device by trained ophthalmic allied health professionals is a safe and cost-effective way to deliver intravitreal injections service.

Keywords

Anti-VEGF, intravitreal injections, nurses, service delivery, safety, retina, age-related macular degeneration

Introduction

Intravitreal injections of anti-Vascular Endothelial Growth Factors (anti-VEGF) are the commonest outpatient procedures completed in the United Kingdom with an estimated 380,000 injections performed annually[1]. This number of injections continues to rise exponentially, owing, in part, to the approval of ranibizumab and aflibercept by NICE. Solely relying on clinicians for this service cannot meet this increasing demand without compromising patient safety. The Royal College of Ophthalmologists recommended training allied health professionals, including technicians and nurses, to administer these injections[2].

Following the success of this execution across several hospitals in the UK[3–5] a similar nurse-led intravitreal injections service was introduced at the Great Western Hospital in 2015 incorporating the use of an injection assist device called Precivia® (FCI Ophthalmics, USA) (Fig. 1)[6]. The device is a polycarbonate mould that fits the limbus with a central window enabling patient fixation

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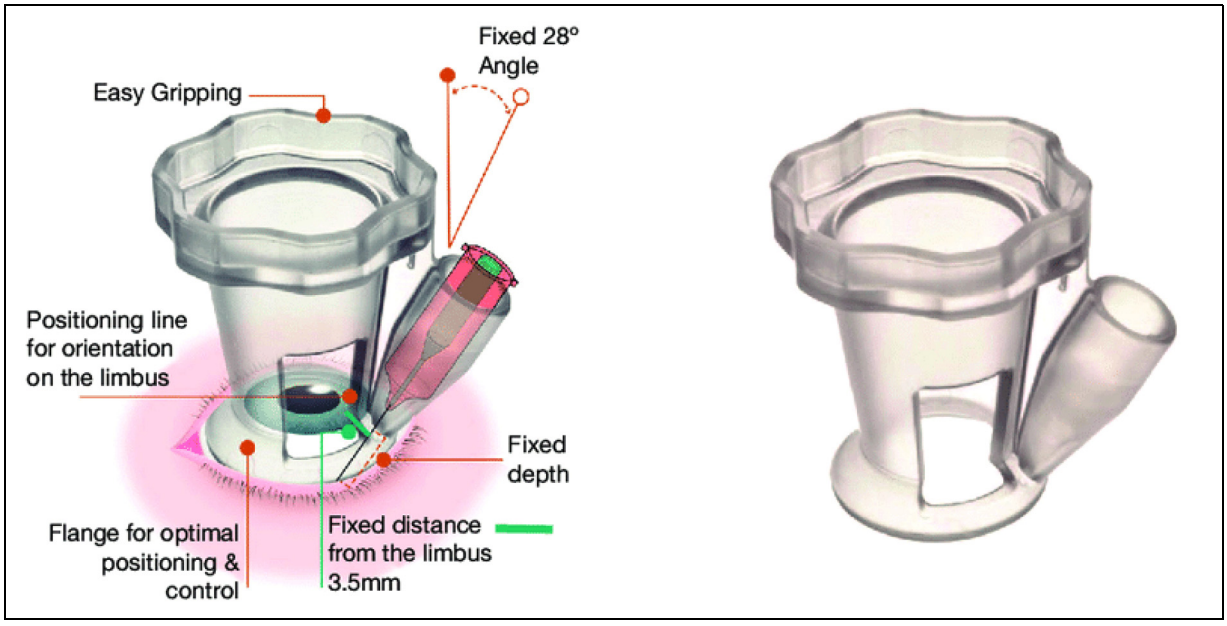

Figure 1. The Precivia® intravitreal injection assist device, manufactured by FCI Ophthalmics USA.

while occluding the patients view of the incoming injection. A 28° angled guided port facilitates entry with a 30-gauge needle at a fixed depth of 5.6 mm to deliver anti-VEGF therapy in a consistent and repeatable manner. We aim to retrospectively review the safety and efficacy of the Precivia® injection device for intravitreal Anti-VEGF delivery by suitably trained ophthalmic nurses.

Methods

Recruitment

Patients were retrospectively recruited from the injection clinic at the Great Western Hospital in Swindon in the period from May 2015 to May 2020. Inclusion criteria consisted of all patients who received intravitreal anti-VEGF

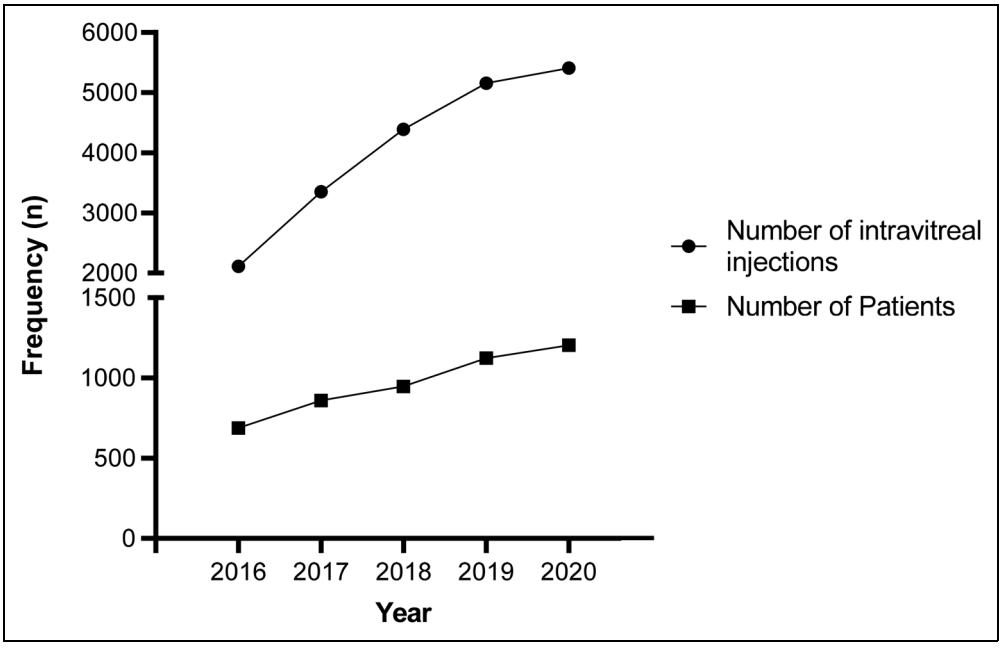

Figure 2. Number of intravitreal injections administered by ophthalmic nurses and number of patients over the five-year study period.

injections. Patients who were excluded (where Precivia® was not used) were:

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

Intravitreal Injection Procedure

5% povidone-iodine solution is first used for periocular antisepsis, following which the Precivia® device is 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 and seal the displaced conjunctiva over the injection site.

Data collection

Data including patient demographics, ocular co-morbidities, indication for treatment, injections and complications were collected from Medisoft EPR (electronic patient record)

Data analysis

All analyses were carried out using GraphPad Prism® 6 (GraphPad Software, California, USA) and SPSS ® Statistics 23 (IBM, New York, USA). Shapiro-Wilk test was performed to assess normality of data. Continuous variables are expressed as mean ± SD for normally distributed data and median (range) for those without a normal distribution, and compared using the independent samples t-test and Mann–Whitney U test respectively. All statistical tests were two-sided and $P < 0.05$ was considered as statistically significant.

Results

In the period May 2015 to May 2020, 2318 patients underwent a total of 26,923 intravitreal injections. Ophthalmic nurses and doctors delivered 20,421 (75.8%) and 6502 (24.2%) injections respectively over the five-year period. The annual number of injections delivered by ophthalmic nurses increased year-on-year from 2112 injections in 2015-2016 to 5410 injections in 2019-2020 (Fig. 2). The annual number of injections and patients in the nursing injection clinic is detailed in Figure 2.

The number of injections by ophthalmic nurses steadily increased from 2015 to 2020, plateauing in the final year. The annual proportion of injections performed by trained nursing staff increased from 49.9% in year 1 peaking to 87.7% by year 4. This was reflected by a corresponding decrease in the number of injections by clinicians decreased from 51.3% to 12.3% (Fig. 3).

The mean age of patients in 2015 was 75.6 ± 12.1 years, increasing to 76.7 ± 12.5 years in 2020 (Table 1). A slight female preponderance was noted, with a male to female ratio of 1:1.01 in 2015, increasing to 1:1.18.

Anti-VEGF injections were most commonly indicated for the management of wet age-related macular degeneration (wAMD), with 1174 injections administered in 2016 increasing to 3634 injections in 2020. Other indications for intravitreal injections, in decreasing frequency, included diabetic maculopathy, retinal vein occlusion and retinal angiomatous proliferations. The percentage of intravitreal injections given for wAMD in this study was the greatest, increasing from 55% to 67% by the end of the 5-year period. This is in contrary to the percentage of injections provided for diabetic maculopathy and retinal vein occlusion that decreased from 26% to 19% and 16% to 10% respectively (Fig. 4).

The overall complication rate remained consistently low ranging from 0.000% peaking at 0.137% in year 3; this was due to six cases of post-injection intraocular pressure spike. These were managed with either topical or oral IOP lowering agents and in one case, an anterior chamber paracentesis was performed. The rates of post-injection IOP spikes then decreased over years 4 and 5 with rates of 0.058% and 0.056% respectively. There was one case of corneal abrasion (0.030%) and no cases of lens touch, retinal detachment or systemic thromboembolic phenomenon in the data set. Figure 5 outlines the annual percentage of complications.

Annual rates of endophthalmitis were as follows: 0.000% (2016), 0.030% (2017), 0.000 (2018), 0.039% (2019) and 0.000% (2020). Three patients over the 5-year study period developed a culture negative, post-injection endophthalmitis giving a rate of 0.015%.

Case 1: An 82-year-old male developed endophthalmitis three days after an intravitreal Aflibercept injection and was treated with intravitreal vancomycin and ceftazidime. Response was initially poor and patient underwent pars plana vitrectomy with further intravitreal antibiotics. Visual prognosis remained guarded as the injected eye was previously amblyopic.

Case 2: An 89-year-old female developed endophthalmitis four days following an intravitreal Ranibizumab injection and was treated with intravitreal vancomycin and ceftazidime, followed by a pars plana vitrectomy with further intravitreal antibiotics. After 12 months, the patient had a spectacle corrected logMAR visual acuity of 0.58, improving to 0.38 through a pinhole.

Case 3: A 60-year-old male developed a culture negative endophthalmitis five days after an intravitreal Aflibercept injection. This was managed with intravitreal vancomycin and ceftazidime. One week later, a pars plana vitrectomy with further intravitreal antibiotics was undertaken. After 12 months, the vision remained poor at hand movements.

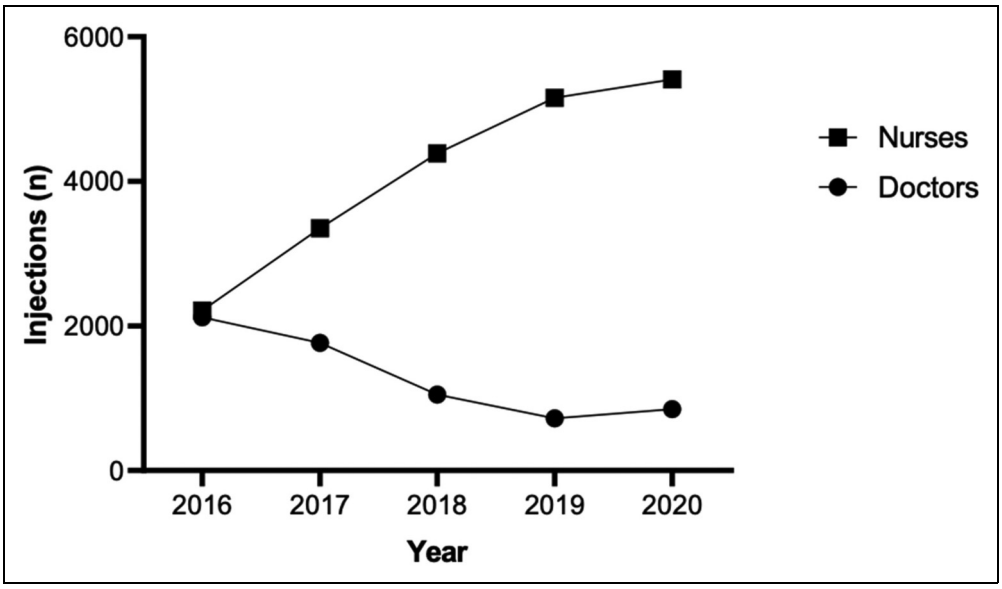

Figure 3. Annual proportion of intravitreal injections administered by ophthalmic nurses vs. doctors

Table 1. Patient demographics including mean age and gender per study year

	Year				
Demographics	2015 - 2016	2016 - 2017	2017 - 2018	2018 - 2019	2019 - 2020
Mean age (SD)	75.6 (12.1)	75.8 (12.2)	76.2 (12.3)	76.7 (12.2)	76.7 (12.5)
Gender (M:F)	1053:1059 (1:1.01)	1610:1742 (1:1.08)	2065:2324 (1:1.13)	2432:2726 (1:1.12)	2484:2926 (1:1.18)

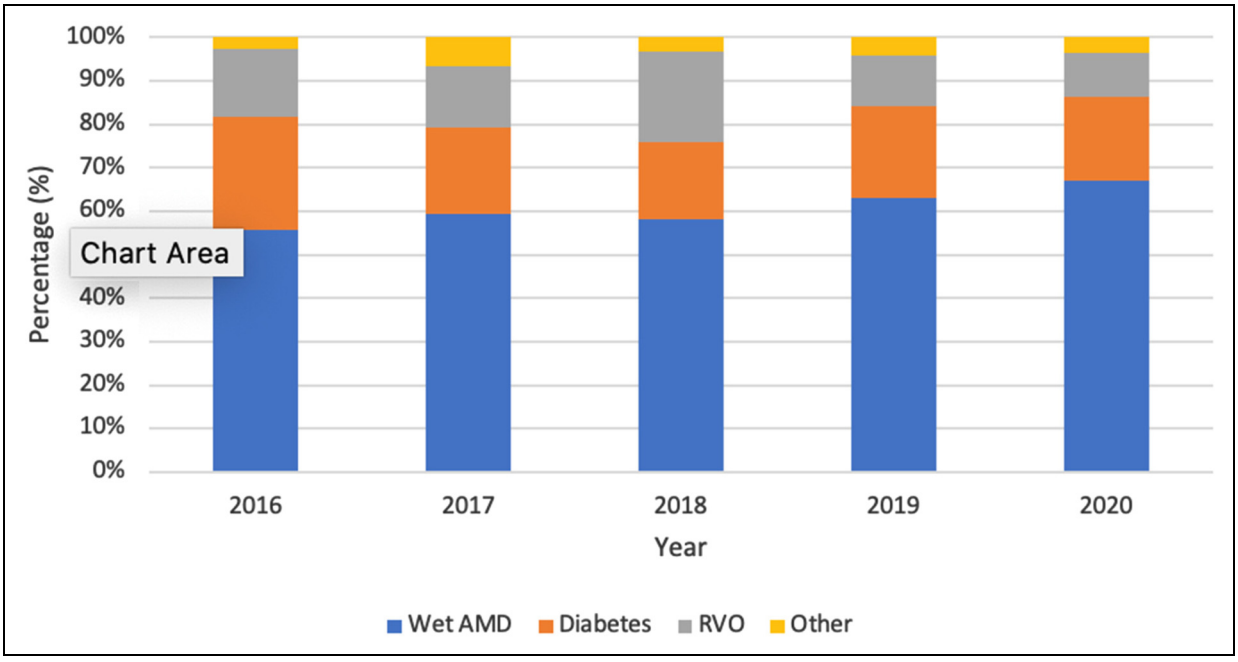

Figure 4. Annual proportion of intravitreal injections administered per indication

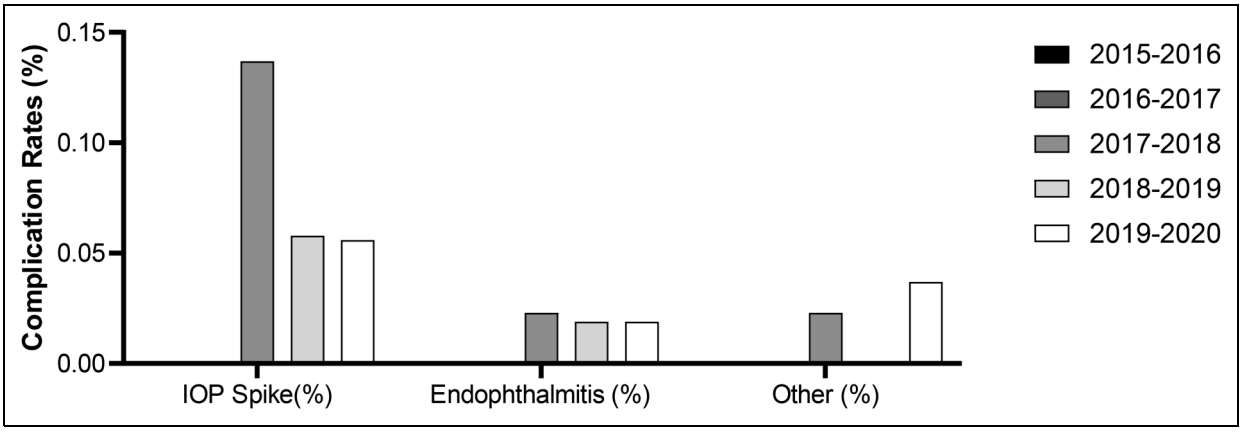

Figure 5. Annual percentage of complication types

Discussion

In the present study, a total of 20,421 intravitreal injections were undertaken over 5 years by trained ophthalmic nurses using the Precivia® assist device with an endophthalmitis rate of 0.015% demonstrating safety and efficacy.

Hasler et al retrospectively reviewed 38,000 intravitreal injections over a three-year-period in Denmark and reported that 63% of injections were performed by nurses with an overall rate of endophthalmitis of 0.36%[7]. In our dataset 75.8% of all intravitreal injections were administered by ophthalmic allied healthcare professionals. However, this was facilitated by the use of the Precivia® assist device, which has already been shown to be well accepted by ophthalmic nurse injectors as well as patients[6]. Hasler et al utilised a costlier approach to injecting consisting of disinfecting the periocular skin with a 5% povidone iodine solution and application of a sterile drape[7]. With use of the Precivia® assist device, the present study bypasses the need for this or other instruments saving expense and time. In a prospective review by Ratnarajan et al, by using the assist device in preference to a traditional pack (containing a surgical drape, lid speculum, callipers, disposable Moorfields forceps, two gallipots, gauze and gauze holders, tray cover and needle disposal block) resulted in a saving of £7.70 per patient[8]. Using these figures, for 20,421 patients in the present study, this would save approximately £157,000 over five years highlighting its economic advantage.

In addition, Hasler et al reported greater complications in patients with kyphosis owing to poor compliance[7], the Precivia® device eliminates the issue of difficult positioning as nursing injectors have been able to utilise this with the patient seated semi-recumbent or in Fowler's position ensuring patient comfort. Contraindications to using the Precivia® device include patients with a history of corneal erosions, previous keratoplasty, patients undergone a trabeculectomy or recent phacoemulsification wherein which the former 'draping' method is utilised.

The national reported rate of post-injection endophthalmitis rate is 0.025%[9], with rates lower for nurses (0.000–0.032%) compared to doctors (0.000–0.042%)[7]. One of the largest safety trials for intravitreal anti-VEGF injections (without use of an assist device) with over 60,000 injections performed had an endophthalmitis rate of 0.02%[10] .The data presented in this study reinforces this with consistently lower rates of endophthalmitis over the five-year period suggesting that endophthalmitis rates does not increase if injections are administered by nurses or by using injection assistant devices such as Precivia®. Similarly, there were no incidences of lens touch (owing to the unique safety design of Precivia®), retinal detachments or systemic thromboembolic events as there has been in other large landmark multicentre trials[11,12].

The department also developed a 12-week training pathway for nurses from induction session to delivering independent intravitreal injection session[13]. Between 2015 and 2020, the number of nurse injectors in the department increased from three to seven while maintaining the standard of injections and keeping patients' satisfaction at a high level[14]. Not only does this up-skill ophthalmic allied health professionals, but leads to a more proficient nurse-led intravitreal injection service and enables more injections to be undertaken.

Limitations of this study include its retrospective design but this has enabled a large sample size to be included and, with a greater frequency of new patients commencing treatment than those completing treatment, the study population remained highly dynamic.

Conclusion

The contribution of nursing staff to the administration of intravitreal injections has steadily increased and is expected to increase further in the coming years. Our study demonstrated a marked increase in the proportion of injections performed by nurses between 2015 and 2020 all using the Precivia® assist device, with a high

standard of safety and patient satisfaction highlighting the success of nurse-led injection services in light of an ever-increasing demand of intravitreal injections.

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Declaration of conflicting interests

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