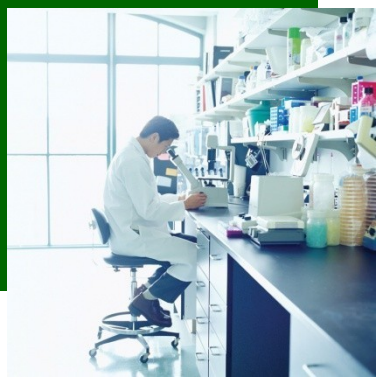
Provincial Health Services Authority

Provincial Retinal Diseases Treatment Program

Quality Update



2020/2021

Provincial Health Services Authority
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Quality Update 2020/21
Provincial Retinal Diseases Treatment Program (PRDTP)

Contents

I. Phase IV Quality Update

The Final Phase IV Quality Review Report and Presentation are now posted on the PHSA website.

Following the completion of three other Quality Reviews (Phase I, II and III), in May 2019, the Ministry and PHSA committed to complete this fourth Quality Review in order to better understand the concern of glaucoma associated with anti-VEGF (vascular endothelial growth factor) treatments and to address any identified modifiable risk factors to improve the program.

The Phase IV Quality Review, completed in March 2020, represents the most comprehensive review completed to date, and is possibly the largest study of its kind, studying 41,000 unique B.C. patients over a 10-year time frame. The review study assessed three glaucoma-related outcomes (glaucoma eye drop medication use, glaucoma laser procedure, and glaucoma surgery) in the context of the following questions:

(1) Is there an increased risk of glaucoma over the years of the program from 2009 to 2018?
(2) How does risk change for patients over time from their first treatment?
(3) What are the factors (patient and non-patient related) which may be contributing to the risk?

The study was supported by an ad hoc quality review working group, consisting of experts in epidemiology, research and ophthalmology (specialists in retina and glaucoma), and an External Expert Advisory Panel. This working group reported into the program's Joint Accountability Committee (JAC) for the duration of the study.

Through this review, there is now a better estimate of risks and a greater understanding of what patient and non-patient factors may or may not be associated with the outcomes. Some key study results:

- The two-year incidence rate of glaucoma surgery was 0.85% (eye-level data), which means about 1 in 120 patient eyes had glaucoma-surgery within two years after starting treatments. While the absolute rates remained low, there was an increase in rates over time between 2009 and 2018.
- The patient-related factors associated with higher rates of glaucoma outcomes included: age less than 75 years old, male sex, retinal conditions of retinal vein occlusion (RVO) or diabetic macular edema (DME), pre-existing ocular hypertension, and prior laser procedures.
- The non-patient related factors associated with higher rates included: patients receiving more than six injections per year (as a cumulative average) and potential differences in components of clinical practice.
- The drug type (including bevacizumab) and pharmacy providers were not associated with higher rates.
- The analyses did not specifically examine the effect of the syringe as all physicians used the same type of syringe i.e. differences in outcomes cannot be explained on the basis of syringe.

Overall, the results are reassuring and confirm that the benefits of the treatments continue to outweigh the potential risks. Without these safe and effective drug treatments, affected patients are at much higher risk of vision deterioration and/or possible blindness. The results of the Phase IV review are generally similar to previous reviews but with a larger sample size, more data spanning over longer periods, and more complex eye-level analyses. There is therefore greater confidence in these Phase IV findings.

The program's JAC includes membership of physician specialists, PHSA and the Ministry of Health and has responsibility for reviewing and guiding the program's quality initiatives and other program management matters. JAC has endorsed the Quality Review Phase IV Report and the associated next steps.

II. Recent PRDTP Quality Activities and Findings:

Two additional quantitative assessments were completed that found that the rate and count of glaucoma laser and surgery procedures have decreased over the past 12-18 months. The data for these pulled from Vital Statistics, the PRDTP database, and the Medical Services Plan (MSP) between January 2009 and June 2020 for all fee codes related to Claim Speciality of Ophthalmology or one or more ICD 9 diagnoses code related to glaucoma. A total of over 42,000 patients were used in review of both laser procedure and glaucoma surgery incidence and crude count.

The first quantitative assessment (A) replicated methodology from Quality Review IV to review the crude cumulative incidence over time for laser procedure and glaucoma surgery. This review separately evaluated both interventions, included more patients than earlier studies, had a longer follow up period, and contained further exclusions to the definition of glaucoma surgery than in previous quality reviews (such as excluding those patients with prior laser/surgery).

A. Crude Cumulative Incidence of Laser Procedure and Glaucoma Surgery
   - For laser procedures, the one-year follow-up rate for 2019 was 0.5%, representing a decrease from 1.0% in 2018.

Table 1. Laser Procedure Crude Cumulative Incidence per 100 Patient by Follow-up Year

Follow-up Years	Years of First Anti-VEGF Injection										
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
1	0.4	0.2	0.4	0.2	0.3	0.5	0.7	0.8	1.1	1.0	0.5
2	0.8	0.9	1.0	0.9	1.2	1.3	1.7	1.9	2.1	2.3	
3	1.5	1.3	1.5	1.5	2.0	2.4	2.9	3.2	3.0		
4	2.1	1.9	2.2	2.2	2.8	3.2	3.6	3.8			
5	2.8	2.5	2.9	3.0	3.3	4.0	4.3				
6	3.5	3.0	3.8	3.5	3.9	4.5					
7	3.8	3.4	4.2	4.1	4.3						
8	4.3	4.0	4.8	4.4							
9	4.7	4.3	5.1								
10	5.0	4.4									

   - For glaucoma surgery, the one-year follow-up rate for 2019 was 1.0%, representing a similar rate of 1.1% for 2017 & 2018. The 2-year follow up surgery rate was 2.0% in 2018, a decrease from 2.4% in 2017.

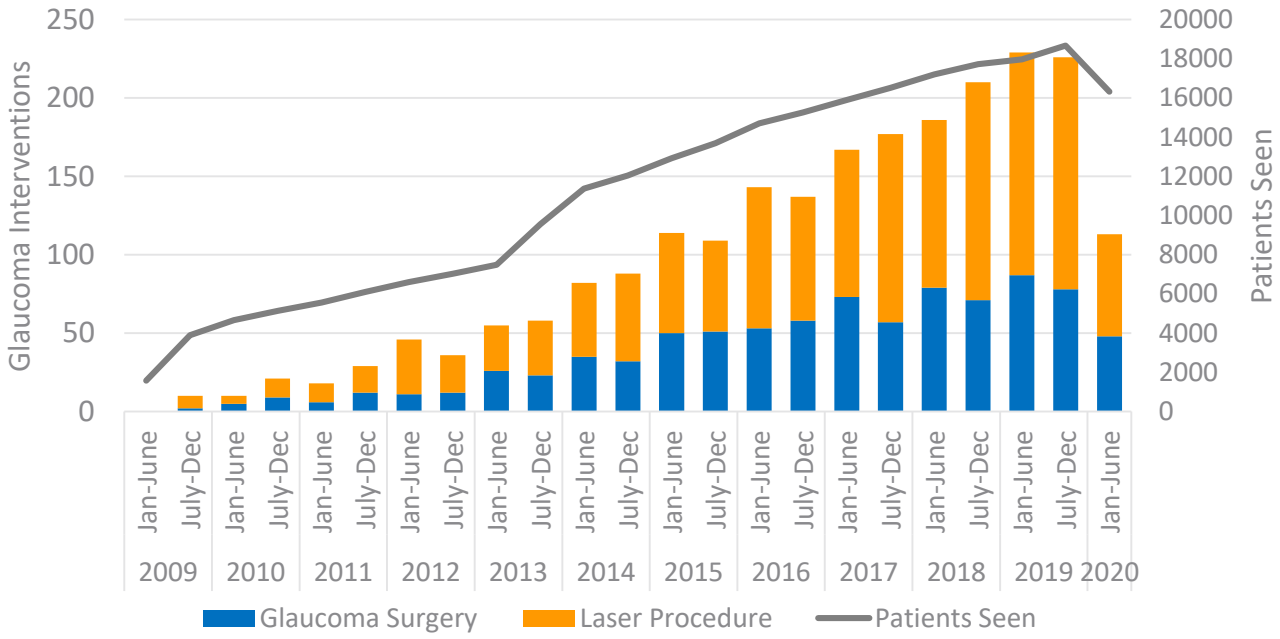
Table 2. Glaucoma Surgery Crude Cumulative Incidence per 100 Patient by Follow-up Year

Follow-up Years	Years of First Anti-VEGF Injection										
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
1	0.3	0.3	0.2	0.3	0.6	0.8	0.9	1.0	1.1	1.1	1.0
2	0.7	0.6	0.8	1.0	1.2	1.6	1.8	2.1	2.4	2.0	
3	1.1	0.9	1.4	1.6	2.0	2.3	2.9	3.4	3.2		
4	1.5	1.4	1.9	2.2	2.8	2.9	3.8	4.1			
5	1.7	1.7	2.1	2.8	3.4	3.4	4.2				
6	2.0	2.1	2.7	3.3	3.9	3.7					
7	2.3	2.6	3.1	3.6	4.3						
8	2.5	2.9	3.4	4.0							
9	2.7	3.1	3.8								
10	2.8	3.3									

The second assessment (B) used the above same dataset, reviewing crude counts of laser and surgery procedures by 6-month time segments.

B. Crude Counts of Laser Procedure and Glaucoma Surgery
- The number of patients seen peaked in July-Dec 2019 and decreased Jan-June 2020, which may be primarily due to COVID restrictions and utilizing Treat and Extend protocols.
- From July-Dec 2019 to Jan-June 2020, the program overall decreased laser procedure counts from 0.8% to 0.4%, representing a 50% relative decrease.
- From July-Dec 2019 to Jan-June 2020, the program overall decreased surgery procedure counts from 0.4% to 0.3%, representing a 25% relative decrease.
- The Jan-June 2020 results for the procedure counts may be influenced by COVID restrictions in terms of total volume.

Figure 1. Crude Count of Laser and Surgery procedures by half year timeframes



The findings from these latest results reassure us again that the risk of glaucoma outcomes remains relatively low - Phase II reporting initially found a 2-year rate of 2.1% for composite endpoint of first event of glaucoma laser procedure or surgery, Phase IV found a two-year glaucoma surgery rate of 0.85% (eye-level data), and the crude cumulative incidence and crude counts for both laser procedure and glaucoma surgery also showed a decline in this most recent reporting to date. Although these cannot be directly compared to one another due to methodological differences, the incidence rate has shown decline across the studies.

Clinical practice interviews were conducted with 27 retinal specialists and 6 glaucoma specialists to understand each specialists' current experience with glaucoma-related issues, and to understand clinical practice similarities and differences. The reviews found:

- Specialists who noted that they had been experiencing more glaucoma-related issues in the past reported that, over the past 12-18 months, they had observed a noticeable decrease in the number and urgency of intraocular pressure cases.
- With respect to potential factors related to why there may be fewer glaucoma-related issues being experienced now compared to the past, the following were reported:
    - Factors that may explain the recent decrease include a combination of: increased attention to diagnosing, monitoring and earlier management of intra-ocular pressure; fewer anti-VEGF drug treatments as treat and extend approach used more widely, with treatment interval extended increased monitoring and earlier management of intraocular pressure; and/or the introduction of drug filtering.
    - Factors unlikely to explain the recent decrease include: injection technique, the use of paracentesis, and/or the introduction of a new syringe for a few users.
- Overall, there were no single and/or shared, clear practice differences identified that explain the variability of glaucoma-related issues.

Summary

Quantitative and qualitative assessments have found that the PRDTP has recently experienced a decline in the number of glaucoma laser and surgery procedures. Some potential factors that might explain this reduction in laser and surgery procedures include:

- increased monitoring and earlier management of intraocular pressure;
- reduced frequency of injections; and/or
- introduction of drug filtering.

Factors unlikely to explain the recent decrease include:

- injection technique,
- the use of paracentesis, and/or
- the introduction of a new syringe for a subset of users.

While recognizing the potential impact of COVID-19 on activity and interventions, the results from these collective assessments are encouraging. Ongoing quality efforts through the program's Quality Action Plan will continue to monitor and optimize the program's safety and effectiveness.

III. Overview of PRDTP Quality Activities

As part of the Phase IV Quality Review, an action plan was developed with the purpose of continuing to understand the relationship with glaucoma risk and to further improve the program. PRDTP is committed to work with our providers and health partners, to continue to improve and support the program.

Although some of the key activities identified in the Action Plan from the Phase IV Quality Review were not possible last year due to competing health system priorities, a number of program quality activities were completed and this work will continue with the formation of dedicated subcommittees within the program.

Table 1. Summary of the Phase IV Quality Review Action Plan and recent PRDTP Quality Review Activities:

Quality Action Plan (March 2020)	**PRDTP Quality Activities Update** (June 2021)
1. Ensure that patients, the public, and the ophthalmology clinical community are aware of the general benefits and risks associated with the PRDTP drug treatments as confirmed through the program quality reviews	• The Phase IV Quality Review Report has been posted on the PHSA website. • A Patient Information Sheet regarding risks and benefits of retinal treatment has been posted on the website for patients and the public.
2. Provide support to program specialists with quality review results and other tools to estimate potential risks for patients	• Program staff met with all program retinal specialists individually to review the Phase IV Quality Review overall results and the specialists' individual results. • Other practice support tools are being prepared.
3. Review provider practices to identify best practices and address potentially modifiable risk factors	• Clinical practice interviews were conducted with all program retinal specialists and some glaucoma specialists.
4. Complete additional quality reviews	• Two additional analytical quality reviews have taken place applying methodology to 2019 data, and reviewing crude counts up to 2020. • Ongoing monitoring will continue, and additional quality reviews are planned to further explore themes from these reports and connected quality topics.
5. Share the findings from the PRDTP Quality Review Studies (Phase I, II, III and IV) at scientific and medical forums	• The program plans to share Phase IV Review findings, as well as other updates, at future scientific and medical forums where possible.
6. Continue to enhance program data collection, monitoring, reporting, and oversight around the program's quality measures related to effectiveness, safety, and program changes	• There are plans to create three new subcommittees. These are Quality, Research and Evaluation, and Drug Supply, and will be established in 2021. These new groups will support ongoing quality, safety and research efforts of the PRDTP.

For further updates on how this work is progressing, please check back on our website page.
(Summary prepared by PHSA/Ministry of Health)