SUBCHAPTER

ISBCS in the Netherlands*

16.3

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Introduction

In the Netherlands, immediately sequential bilateral cataract surgery (ISBCS) was not performed routinely in hospitals or eye clinics until 2021, except by a few private practices. This is mostly due to the fact that up to 2021, the national cataract guideline of the Dutch Ophthalmologic Society (Nederlands Oogheelkundig Gezelschap; NOG) advised against the performance of ISBCS, based on the presumed risk of bilateral endophthalmitis and potentially worse refractive outcomes.[1] The 2016 Dutch cataract guideline indicated that if a patient was to undergo cataract surgery in both eyes, a period of at least 2 weeks had to be applied between first-eye surgery and second-eye surgery (delayed sequential bilateral cataract surgeries DSBCS). In addition, a physical examination of the first eye had to be performed at 1 week after first-eye surgery, to examine the surgical results prior to second-eye surgery. In order to monitor and enforce the application of the national guideline in clinical practice, these recommendations were used to develop national quality indicators by a quality committee of the NOG. For example, some of the indicators to measure the quality of cataract care derived from the 2016 guidelines included:

(1) the percentage of patients that underwent cataract surgery in both eyes with a period of 2 weeks between surgeries.
(2) the percentage of patients who had an ophthalmologic examination at 1 week after first-eye surgery prior to second-eye surgery.

These quality indicators were measured using hospital registrations on healthcare activities, the Dutch reimbursement registry system, and the Dutch National Cataract Registration database.

Discussion

Up to 2021, ISBCS was only suggested by the national guideline as an option in selected cases, such as in patients with perioperative medical risks who had to undergo surgery using general anesthesia, or in patients with bilateral acute angle closure glaucoma due to bilateral cataracts. This advice was in line with other national guidelines at that time, like the national guideline from the United Kingdom (The Royal College of Ophthalmologists; 2010) and the Canadian national guideline (2008). In addition, the Dutch national guideline described a lack of high-quality evidence in available literature, mainly with

regard to the safety of ISBCS compared to DSBCS. Therefore, a large multicenter noninferiority randomized controlled clinical trial to investigate the safety, efficacy and cost-effectiveness of ISBCS versus DSBCS in the Netherlands, called the BICAT-NL study (Bilateral Cataract in the Netherlands), was initiated.[2]

The BICAT-NL trial was funded by a research grant awarded by ZonMw, an independent organization of the Dutch government for funding of health care innovations and healthcare research.[2] The study received approval from the medical ethics committee in 2018 and was conducted from September 2018 until July 2020. A total of 865 patients were recruited from 10 hospitals across the Netherlands (Fig. 16.3.1) and randomized for either ISBCS or 2-week interval DSBCS. The primary objective of the study was to evaluate the difference in proportions of second eyes with a refractive outcome within 1.0 diopter (D) of target refraction at 4 weeks after surgery between treatment groups. Secondary outcomes of the study included refractive outcomes within 0.5 D, uncorrected and best-corrected visual acuity in second eyes, overall (bilateral) complications, patient reported outcome measures (PROMs) and cost-effectiveness of ISBCS versus DSBCS.[2] Results of the trial showed that ISBCS was not inferior to DSBCS with regard to refractive outcomes within 1.0 D and 0.5 D of target refraction in second eyes. Moreover, ISBCS was noninferior with respect to uncorrected and best-corrected visual acuity, and complication rates did not differ between both treatment arms. PROMs

FIGURE 16.3.1

Overview of hospitals that participated in the study on Bilateral Cataract in the Netherlands (the BICAT-NL trial). (1) Maastricht University Medical Center (MUMC$^+$), Maastricht; (2) Amphia Hospital, Breda; (3) Canisius Wilhelmina Hospital, Nijmegen; (4) Deventer Hospital, Deventer; (5) Elisabeth TweeSteden Hospital, Tilburg; (6) Gelre Hospital, Zutphen; (7) Isala Clinic, Zwolle; (8) Medical Center Haaglanden, Den Haag; (9) Medical Spectrum Twente, Enschede; (10) Zuyderland Medical Center, Heerlen.

were measured using the validated NEI-VFQ-25 and Catquest-9SF questionnaires, and no significant difference between ISBCS and DSBCS patients was found at 3 months after surgery. Both healthcare costs and costs from a societal perspective were calculated to be lower for ISBCS compared to DSBCS. In terms of cost-effectiveness, using the incremental costs from a societal perspective per quality-adjusted life year (QALY), ISBCS was found to be superior to the delayed procedure [personal communication; data not published yet].

In addition to this multicenter randomized controlled trial, a survey was performed on the attitude of Dutch ophthalmologists toward ISBCS. In the Netherlands, a national survey to evaluate cataract and refractive surgery practice patterns among Dutch ophthalmologists is performed annually by the NOG. In May 2020, additional questions on the attitude toward performing ISBCS were added to this survey. Results of the 2020 survey showed that 27.3% of surgeons performed ISBCS. However, in 90.3% of these surgeons, ISBCS was done for only 1 to 5 patients per month, which could be explained by the advice regarding selected cases as described in the national cataract guideline. Only a few surgeons indicated that they perform ISBCS on a more routine basis (1.6% of surgeons performed ISBCS in 16–20 patients per month and another 1.6% of surgeons performed ISBCS in over 20 patients per month) [personal communication; data not published yet]. Still, 47.6% of surgeons responded that they would consider performing ISBCS routinely in the near future. Since the questions on ISBCS were not implemented in the survey before 2020, and since the COVID-19 pandemic was ongoing during this first survey, it was not possible to evaluate the magnitude of the impact of the pandemic on the willingness of surgeons to perform ISBCS.

Following the results of the BICAT-NL trial, some of the centers that participated in the study started to implement ISBCS into routine practice by the beginning of 2021. However, to encourage national implementation of ISBCS, an adjustment of the Dutch national cataract guideline recommendations on ISBCS is needed. The national guideline is currently being revised, and a new version is expected to be approved by the NOG in 2021. In this new version, recommendations are likely to be as follows:

(1) ISBCS can be considered in suitable patients
(2) if the ISBCS procedure is chosen by the patient, it should be performed as two separate aseptic procedures, and by adhering to the "*i*SBCS general principles for excellence for ISBCS 2009."[3]
(3) deferring second-eye surgery must be considered in the event of complications arising during first-eye surgery [personal communication with the national cataract guideline workgroup].

Since available literature on ISBCS mainly includes patients without ocular comorbidities and without an increased risk of surgical complications, these recommendations will be limited to that particular patient population. In addition to these revised recommendations, the quality indicators that are inherent to the DSBCS procedure, as previously mentioned, will be omitted.

Although the COVID-19 pandemic may facilitate a faster adaptation of ISBCS in Dutch hospitals due to advantages like reduced numbers of patient visits to the hospital, some barriers for national implementation can arise. For instance, it has been a generally valid principle in the Netherlands for decades that surgery should not be performed in both eyes unless strictly necessary, and this has been an indicator of quality for cataract care for a long time. So, a paradigm shift is needed, and it is likely that some ophthalmologists (or hospital administrators) will remain reluctant to adopt ISBCS. Nevertheless, the NOG can facilitate in creating awareness for the adjusted guidelines and in providing reliable information on the safety and effectiveness of ISBCS to improve implementation.

Furthermore, logistic adaptations that are required in the operating room to be able to adhere to the *i*SBCS general principles, and a potential negative influence on reimbursement rates provided by healthcare insurance companies, could form barriers for implementation of ISBCS. To date, Dutch cataract surgeons receive full reimbursement for the second eye when performing surgery on both eyes on the same day. However, the current reimbursement system is arranged in such a way that hospitals and surgeons are paid by healthcare insurance companies according to a code that represents a certain combination of diagnosis, treatment, and follow-up. Currently, this reimbursement code assumes that surgery is performed on each eye on separate days, according to the DSBCS principle. However, when national guidelines omit the recommendation against ISBCS and the quality indicators preferring DSBCS, a revision of the reimbursement system is likely to be carried out. This has to be done in careful collaboration with healthcare providers (cataract surgeons represented by the NOG), health insurance companies, and the Dutch healthcare authority (an independent Dutch governing body supervised by the Dutch Ministry of Health that monitors healthcare providers and insurance companies), in order to prevent negative reimbursements rates that impede national implementation of ISBCS.

Summary

The BICAT-NL study has resulted in a much more favorable outlook on ISBCS in the Netherlands since 2021 compared to previously. However, a number of other procedural, regulatory, and financial reimbursement factors now remain to be addressed before ISBCS is likely to be adopted enthusiastically all across our country.

Statement of financial interest

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