Evaluation of glaucoma surgery efficiency

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Introduction. *The choice of the assessment criteria is important to evaluate the glaucoma surgery efficiency.*
Purpose. *To develop a comprehensive assessment and to propose a scoring scale of glaucoma surgery efficiency.*
A comprehensive system to evaluate glaucoma surgery efficiency was proposed as a ratio of hypotensive effect and safety of operation. Surgical success was defined as complete (IOP ≤ 15 mmHg without glaucoma medication, reduction in IOP ≥ 30%); qualified (IOP≤ 15 mmHg with glaucoma medication, reduction in IOP from 20 % to 30 %) and poor (IOP > 15 mmHg with glaucoma medication, reduction in IOP to 20 %), considering a number of medications pre- and postoperatively, duration of hypotensive effect, reoperations. Safety of the surgery was evaluated as nature and number of intra- and postoperative complications, particularly those that led to the irreversible lost of visual acuity. The cost of operation, the time of rehabilitation, additional manipulations also should be considered. The scoring scale of efficiency of glaucoma surgery was proposed as follows: 4-6 scores, high efficiency of operation; from 1 to 3 scores, mean efficiency of operations; less than 1 point, the efficiency of operations is low.
Conclusion. *Unified criteria are essential for an objective evaluation of glaucoma surgery efficacy. Such success criteria as hypotensive effect and its intensity, number of additional medication, hypotensive effect duration, additional procedures and reoperations, complications and their nature, and vision acuity loss rates need to be considered for unified complex assessment of glaucoma surgery success.*

Key words: glaucoma surgery, success criteria, hypotensive effect, safety

Introduction

The choice of the assessment criteria is important to evaluate the efficiency of glaucoma surgery. Rotchford A. P. and King A. J. have performed a systematic review of the literature for a five-year period and shown that there are as many different definitions of success after glaucoma surgery as publications on the subjects. According to this data success rates varied from 36.0% to 98.0%. Such a wide range of success can be explained by different criteria of indications for glaucoma surgeries, patients' choice, different diagnoses, surgeon proficiency, and variability of postop treatment, and in no small measure by difference of criteria used to define success [1]

Different authors used different criteria even in such seemingly a clear issue as a hypotensive effect of surgery. Thus, a great number of authors define surgery as successful if intraocular pressure (IOP) achieves < 21 mmHg by Goldman which is approximately < 26 mmHg by Maklakov [2, 3, 4]. Formally, this is an upper limit of normal static IOP. However, achieving the upper limit normal IOP does not guarantee the stabilization of glaucomatous process. That's why many authors define surgical success as IOP achieving ≤18 mmHg, ≤15 mmHg, and even ≤12 mmHg by Goldman [5, 6, 7, 8]. In Ukrainian literature there is also a clear tendency to define success rate of IOP after surgery as a lower limit of average normal rate (26 mmHg by Maklakov) [9].

Thus, definition of postoperative success rate of IOP is quite subjective. As a rule, hypotensive effect of surgery is assessed according to three grades as follows: complete surgical success (achieving target IOP without additional hypotensive therapy), qualified surgical success (achieving target IOP with additional hypotensive therapy), and failure (not achieving target IOP). The latter definition is not entirely correct since it may be a success but insufficient since target IOP is not achieved. To our opinion, a more proper definition is poor hypotensive effect.

As a matter of practice, hypotensive effect of the surgery cannot be assessed not regarding the use or non-use of additional medication. Herewith, it is important not only to note the need to use hypotensive drugs but to define the number of medications used to achieve target IOP [10, 11, 12, 6]. For example, in two equivalent groups of patients with an equal rate of IOP after surgery, hypotensive effect is higher in the group where less medication is used after surgery.

Another criterion of surgical success is a proportion of IOP lowering as compared to pre-operative IOP. According to the target IOP formula, in case of conservative glaucoma treatment, the reduction should be 25-30% as compared to IOP rate when glaucomatous changes appeared in the optic nerve. As for glaucoma

surgery, European Glaucoma Society recommends to define effective a reduction by 20% and more from baseline [13]. Such a difference in assessment of drug and surgical treatment can be explained by the fact that the majority of patients have already been taken hypotensive therapy preoperatively. That's why additional 20% reduction from preop IOP is rather effective taking into account hypotensive therapy. Also, different authors use different criteria (>20%; >25% and ≥30% IOP reduction) to assess the surgical success in this regard [2-6, 11, 12, 14, 15].

Anatomical criteria of success in fistulizing antiglaucomatous operations are the presence of a filtering bleb and its state (apparent, flat, cystic and etc.), or, vice versa, the absence of the filtering bleb. Herewith, hypotensive effect of the surgery is directly associated with the presence of the filtering bleb [16].

Not least important for surgical success is duration of the hypotensive effect as well as the need to re-perform antiglaucomatous operations. A direct hypertensive effect of the surgery is often assessed at 3-6 months after operations; a remote effect is assessed at 2-5 years. It is not uncommon that the reoperation is assessed as surgical failure 10, 7].

However, reoperation associated with a reduction or loss of the hypotensive effect at five years cannot be defined as surgical failure [2, 3]. And, if anything, the duration of the hypotensive effect of the surgery for five years indicates high surgical success.

In the national literature, with the purpose of studying the hypotensive effect of antiglaucomatous operations, indices of fluid outflow are often defined among which the coefficient of easiness of fluid outflow is most important. However, outflow rates do not determine the success of antiglaucomatous operations and, in our opinion, it's inappropriate to use them as assessment criteria.

The hypotensive effect reflexes only one side of efficacy of antiglaucomatous operations. Assessing surgical success it is important to weigh ratio of the hypotensive effect and safety of surgery (complications, their occurrence and severity). For example, The Elliot trephining operation was very effective against the hypotensive effect but accompanied by many severe complications.

Despite the common tendency to use mini-invasive surgeries, modern glaucoma surgery is still characterized by certain complications, intra- and postoperative. One of the common intraoperative complications is hemorrhage into anterior chamber [17].

The most common postoperative complications of "penetrating" antiglaucomatous operations are choroidal detachment, shallow anterior chamber, and postoperative hypotony[18, 19]. Against this background, there is often observed inflammation with the formation of posterior synechiae and cataract progression. In hypotony, filtration bleb is formed badly and inflammation causes failed filtration.

Failed filtration is a postoperative complication leading to the loss of the hypotensive effect [20, 21, 22]. To form a filtration bleb, massage of the eyeball is performed. Needling is used if filtration is failed [21, 22]. Surgical revision of failed filtration is also an ordinary procedure [23].

Another postoperative complication is a hypernormal hypotensive effect that can lead to hypotensive maculopathy. That's why some authors define IOP reduction to 6 mmHg by Goldman as surgical failure criteria [15].

Cataract progression is also a late postoperative complication [24, 25].

The most severe late complication of penetrating glaucoma surgery is endophthalmitis that can develop against the background of blebitis (filtration bleb inflammation) after mitomycin using [26].

Surgical complications in glaucoma can be divided in those causing temporary vision acuity loss and those leading to irreversible loss of vision acuity. English-speaking papers often use the criterion of loss of 2 lines of Snellen acuity [5, 4]. This criterion is rather unspecific, but, alongside this, it clearly characterizes safety of surgery. Otherwise, vision loss of 2 lines of Snellen acuity variously characterizes vision loss if preoperative vision acuity was e.g. 1.0 and 0.5.

Beside the efficacy and safety of the operation, the cost of surgery should also be taken into account, in particular the cost of medical supplies, length of hospital stay, period of temporary incapacity, follow-up visits, additional procedures (massage, needling, filtration revision) or glaucoma reoperations, additional hypotensive therapy after surgery, and the presence of postoperative pathologic changes (e.g. the presence of cystic filtrating bleb). All these, together with surgical cost, determine the life quality of a patient. Thus, Patel HY et al have demonstrated that economic cost of Ex-PRESS shunt implantation was $ 956 greater than that of trabeculectomy. The postoperative cost (follow-up visits, additional procedures, and medications) had no significant difference ($485 vs. $609). Authors have concluded that surgical cost needs to be considered along with efficacy and safety of the surgery [27].

The purpose of the present study was to perform complex assessment and to propose a scoring scale of glaucoma surgery efficiency.

A complex system for assessment of surgical efficiency is proposed as a proportion of the hypotensive effect, surgical safety and life quality of patients.

I. Hypotensive effect at half a year after surgery:

1) Complete success was defined as achieving target IOP with no medication (IOP ≤20 mmHg by Maklakov or ≤15 mmHg by Goldman and ≥30% reduction of IOP)

2) Qualified success was defined as achieving target IOP with medication (IOP ≤20 mmHg by Maklakov or ≤15 mmHg by Goldman and 20-30% reduction of IOP)

3) Poor success was defined as achieving target IOP with medication (IOP ≤20 mmHg by Maklakov or ≤15 mmHg by Goldman and < 20% reduction of IOP)

Additional surgical success criteria:

1) Number of intro- and postoperative medication
2) Stability of the hypotensive effect as IOP rates at time points of half a year, two and five years from baseline
3) Glaucoma reoperations at half a year, two and five years from baseline

II. Surgical safety:

1) Hypotony (IOP ≤12 mmHg by Maklakov or ≤7 mmHg by Goldman)
2) Nature and number of intra- and postoperative complications including reoperation due to cataract at 1 year.
3) Vision acuity loss rate (< 20% and >20%) from baseline

III. Life quality of patients:

1) Surgical cost
2) Rehabilitation period
3) Additional procedures
4) Additional medication

The next stage in unified assessment of glaucoma surgery efficiency is creating a scoring scale of surgical efficiency. For that, we propose a scoring system for assessment of surgery as follows (Table 1):

Table 1. Scoring scale according to surgical success criteria

Success criteria	Scores		
Hypotensive effect at 6 months	**Complete**	**Qualified**	**Poor**
Hypotensive effect at 6 months	Complete +4 scores	Qualified +2 scores	Poor 0 scores
Stability of hypotensive effect	> 5 years +2 scores	From 2 to 5 years +1 scores	< 2 years 0 scores
Complications causing temporary vision acuity loss	No 0 scores	Cataract development at 1 year -1 score	Hypotony (IOP ≤12 mmHg by Maklakov or ≤7 mmHg by Goldman)-2 scores
Irreversible vision acuity loss	No 0 scores	> 20%-1 score	< 20% -2 scores

The scoring scale of efficiency of glaucoma surgery was proposed as follows: 4-6 scores, high efficiency of operation; from 1 to 3 scores, mean efficiency of operations; less than 1 point, the efficiency of operations is low.

Case 1. Complete hypotensive effect at 6 months from baseline; hypotensive effect for 4 years (+1 score). No complications leading to temporary or irreversible vision acuity loss.

Total +5 scores. Surgical efficiency is high.

Case 2. Qualified hypotensive effect (one hypotensive medication) (+2 scores); hypotensive effect for 1 year (0 score). No complications leading to temporary or irreversible vision acuity loss. Total +2 scores. Surgical efficiency is mean.

Case 3. Qualified hypotensive effect (two hypotensive medications) (+2 scores); hypotensive effect failed within 1 year (0 score). Cataract development resulted in glaucoma reoperation combined with cataract phacoemulsification within 1 year (-1 score). Irreversible vision acuity loss by 20% (-1 score). Total 0 scores. Surgical efficiency is low.

Conclusions

1. Unified criteria are of great importance for objective assessment of glaucoma surgery efficiency
2. Efficacy criteria which need to be considered for unified complex assessment of glaucoma surgery efficiency are: hypotensive effect and its intensity, number of additional medication, hypotensive effect duration, additional procedures and reoperations, complications and their nature, and vision acuity loss rates.
3. Criteria and a scoring scale proposed need to be discussed; they can be used as a basis for unified complex system for assessment of glaucoma surgery success.

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